Drug Card Pre-Application Conference

Responses to questions posed at the Drug Card Pre-Application Conference & email

NOTE: Due to the extraordinary attendance at the conference, interest in this program, and resulting large number of questions received by us, we are answering questions on a rolling basis. If you do not see the answer to your question at this time, please check back frequently for updates. Also, some of the questions were similar to others, in which case we answered only one version of the question. Therefore, please carefully read through all of the questions and answers.

We are making every effort to answer all questions as quickly as possible.

Last Updated: February 27, 2004 ***(See Question #31 under Drug Card Offering)***

Topics:

Solicitation, Application Process & Timing (Endorsement)

1. What is the date by which potential applicants are required to submit to CMS a notice of intent to submit an application?

    A. CMS has changed the date by which potential applying organizations are required to submit to CMS their notice of intent to apply (including a completed CMS Connectivity Request). **Potential applicants must submit to CMS a notice of intent and a completed CMS Connectivity Request on or before January 7, 2004.** Please review the revised language (as of December 23, 2003) in Section 2.1 of both solicitations for clarified instructions concerning the submission of these two documents.

2. Will CMS accept applications from organizations that do not submit a timely notice of intent to apply?

    A. No. CMS will not consider an application for approval from an entity that has not submitted a timely notice of intent to apply. CMS has adopted this policy because only Applicants who submit a timely CMS Connectivity Request (as part of the notice of intent) can eventually demonstrate their ability to exchange data with CMS in time to begin enrollment activities on May 3, 2004. Please note that entities that submit notices of intent to apply are not obligated to submit an application for approval to CMS.

3. What specific dates begin and end for the 30-day period to comment on the drug card regulation?

    A. The comment period for the Medicare Program: Medicare Prescription Drug Discount Card interim final rule began on December 15, 2003 and will end on January 14, 2004.

4. Can a prescription benefit manager (PBM) provide a discount card to Medicare recipients without being part of a managed care organization?

    A. PBM may operate its own drug card program as long as it meets all qualifications for Medicare approval. No partnership with a managed care organization is required for Medicare approval.

5. In order to be a provider of discount cards does a PBM have to be presently providing prescription cards to managed care organization?

    A. No.

6. Can an endorsed sponsor have multiple programs to accommodate private label customers? If not, do each of these customers need to submit a separate application for endorsement listing our organization as a subcontractor to meet the program requirements?

    A. An Applicant may submit applications to operate multiple approved programs; each with is own exclusive Medicare enrollment. The Applicant could then include private label customers' names and logos on the approved card's information and outreach materials, provided CMS approved such materials. However, in each case, the Applicant's name would be required to be displayed on all materials on which the

Medicare name and/or logo appears since CMS is approving only the entities that submit the applications for approval, not the entities with which an Applicant subcontracts. Alternatively, private label customers wishing to offer an approved drug card without identifying the subcontractor managing the pharmacy benefit may each submit an application of their own, and identify the subcontractor managing the pharmacy benefit. In such instances, assuming a successful application, CMS will provide Medicare approval for the private label customer, whose drug card can be marketed with the Medicare name and logo, but without identifying the subcontractor.

7. Can a company submit more than one application? For example, assume we want to offer two discount card products, each at different costs to the Medicare member. Do we include both of these in one application, or do we submit two different applications? Can product variants (for example offering different network sizes, annual fees, lists of discounted drugs, etc.) be submitted under the same application?

   A. There is no limit to the number of drug card programs for which an organization may submit an application for Medicare endorsement. We encourage Applicants to submit only one application describing all the discount cards they may offer. However, Organizations may elect, for their administrative convenience, to submit a separate application for each program for which they are seeking approval.

8. Will organizations that participate in the Discount Card be at an advantage when the new Medicare drug benefit becomes effective in 2006?

   A. According to the authorizing legislation for both the Medicare-approved discount card drug program and the Part D (Medicare drug benefit), CMS will not consider operation of an approved discount card as a qualification for participation as a prescription drug program under Part D. However, card sponsors offering an approved drug card whose performance results in significant customer satisfaction may find that that reputation provides a significant advantage in competing for enrollees once the Part D programs are open for enrollment.

9. If we want to sponsor more than one plan, can we submit another plan after the application is in?

   A. CMS will accept no applications for Medicare approval after January 30, 2004. However, entities that have already submitted an application prior to that date may submit an additional application (or an amendment to the submitted application) on or prior to January 30, 2004.

10. If the applicant is a 50-50 joint venture and uses a 100%-owned subsidiary of one of its owners (i.e., an affiliate) to meet an applicant requirement, must the applicant have a contract with the affiliate?

    A. In the scenario you describe, since a subsidiary is a separate business entity (e.g., is incorporated, has its own board of directors), the Applicant must provide evidence of a contract between the subsidiary and the Applicant if the subsidiary is to provide services related to the operation of the Applicant's approved drug card program.

11. Should the Notice of Intent be provided at the organization level or the plan level?

A. The notice of intent should be provided by the organization seeking to offer the approved discount card program. With respect to Medicare managed care organizations, the notice should be provided by the managed care organization, not the managed care plan. Managed care organizations wishing to offer both an exclusive Medicare managed care plan drug card as well as general drug card available to all beneficiaries residing in the card program's service area need submit only one notice of intent to apply. Note that Medicare managed care organizations wishing to offer these two types of drug cards must submit two separate applications, one using the general solicitation and another using the Medicare managed care solicitation.

12. Do you anticipate there being any flexibility in the January 30, 2004 application deadline?

A. To meet the six-month implementation deadline established by the Medicare-approved drug card program's authorizing statute, CMS has adopted an aggressive application review process. The January 30, 2004 deadline is crucial to ensuring that both card sponsors and CMS will be prepared to make this program fully operational (i.e., discounts and transitional assistance (TA) available to beneficiaries) by June 1, 2004.

13. To whom does the notice of intent get sent?

A. Both the notice of intent and the CMS Connectivity Request are to be sent to Kim August. Please see our December 23, 2003 revisions to the solicitations for more details.

14. How many subcontracts may an Applicant use to meet the drug card program qualifications?

A. There is no limit on the number of entities with which an Applicant may subcontract to meet the qualifications for Medicare approval of their discount drug card program. However, please note that in the case of the Covered Lives requirement, one subcontractor must meet the 1 million lives qualification by itself. For example, An Applicant may not use two subcontractors, each with 500,000 covered lives to meet the qualification. Similarly, an Applicant using a contractor to meet the three years experience requirement must use entities that by themselves each have three years experience. For example, an Applicant combining three entities with one-year experience each would not meet the experience qualification.

15. To be an endorsed sponsor for Medicare Part D in 2006, does the sponsor need to participate in the discount drug program in 2004 and 2005.

A. No.

16. How do Medicare managed care organizations file a notice intent to apply with CMS?

A. Medicare managed care organizations are to follow the same notice of intent to apply filing procedures as all other Applicants. Please refer to Section 2.1 of the updated

version (December 23, 2003) of the Medicare managed care organization solicitation for clarified information on the filing of the notice of intent to apply.

17. Do those of us applying for special approval have to get out letters of intent in at the same time as everyone else?

A. All organizations that may apply for Medicare approval (regardless of the type of program for which they are seeking approval – managed care, special approval, etc.]) must submit on or before January 7, 2004 a notice of intent to submit an application (including the CMS Connectivity Request) to CMS. Applicants are asked to meet this deadline so that they can ensure that they can meet the connectivity qualifications of the program according to CMS' announced approval schedule. Please note that a notice of intent does not obligate an organization to submit an application to CMS. Additionally, if necessary, the Connectivity Request can be updated after the January 7 date as new information becomes available to the applicant. The January 7 information submitted should reflect the best response possible at that time.

18. Do contracts for rebates or discounts with pharmaceutical manufacturers need to be reviewed or approved by CMS. Do templates of rebate contracts need to be submitted to CMS?

A. Sponsors are required to attest to the existence of manufacturer contracts that are applicable to the drug card program, including identifying all such manufacturers. The minimum requirement is one contract. CMS requires sponsor applicants to provide contracts between the sponsor and subcontractor (if any) that negotiates pharmaceutical manufacturer rebates. CMS does not expect sponsors to provide manufacturer rebate contracts. Rather, sponsor applicants must provide a discussion about these contracts, as required by the application requirements in Section 3.2.2. of the general solicitation, including the sponsor must attest that such contract(s) exits and with what manufacturer(s).

19. If a card sponsor represents several programs, will the enrollment, payment information and price comparison files all be managed by the card sponsor or some of these functions be managed at the program level?

A. The card sponsor is the legal entity that submits an application for approval to CMS and, if successful, will enter into a contract with CMS to offer a Medicare-approved drug discount card. The discount card program is the product the card sponsor will offer to Medicare enrollees. This product is made up of a set of features, including drug prices and a network of pharmacies, to which Medicare beneficiaries will have access to by virtue of their enrollment in a card sponsor's program. Therefore, since the card sponsor is the entity with which CMS will contract to operate a Medicare-approved drug card, it is expected that the card sponsor will administer the enrollment, payment information, and price comparison files related to the operation of the sponsor's product, the Medicare-approved drug card program. Card sponsors are certainly permitted to engage subcontractors to perform required tasks related to the drug card operation. However, accountability for the quality and performance of the drug card program will remain with the card sponsor with whom CMS contracted.

20. If a card sponsor represents several programs, can each program have a different presence (name) on the Medicare price

comparison web site and can each program have a different discount network rate?

A. Card sponsors may operate several Medicare-approved drug card programs. Information on the CMS-operated price comparison web site will be displayed for each approved program, not for each card sponsor. For example, a card sponsor that receives Medicare approval for three separate drug card programs will have each of its three programs displayed under their individual program names. There would not be just one listing for that card sponsor. Each approved program may have its own unique set of discounts on its own formulary of covered drugs, as long as such discounts and formularies meet CMS' qualifications for approval.

21. Do you have restrictions on co-branding? It seems clear that there must be a single entity that is the endorsed sponsor. If the M+C applies as an exclusive card sponsor does that preclude them from co-branding. Can one of their partners, such as a PBM, have their brand concurrently on the materials/cards? Can an approved PBM put its client's logo/program name on the materials? If either of these scenarios is possible what are the application requirements and materials approval requirements and how are they different from a regular process. Can one set of materials with a "blank" for the potential partners logo be submitted for approval and then have those approved materials co-branded for all partners?

A. Health plans or other organizations that add their own 'endorsements' to a Medicare-endorsed card program may add their own brand in addition to but not instead of the card sponsor's label for the Medicare-endorsed discount card program. The card sponsor's name would be required to be displayed on all materials on which the Medicare name and/or logo appears since CMS is approving only the entities that submit the applications for approval, not the entity offering its own endorsement. The endorsed Card Sponsor will be required to ensure that other endorsing organizations label the actual card and make reference to the Medicare-endorsed card program in a manner that is consistent with the CMS information and outreach guidelines, how these materials do not have to be submitted for a separate review.

22. The Interim Rule requires that applicants submit audited financial statements as part of the application for approval to participate as an endorsed Medicare Prescription Discount Prescription Drug Plan. Privately held corporations do not have audited financial statements. What documents will CMS allow in lieu of these documents. And part two of this question. Are the financial documents of provided by private held corporations for the satisfaction of requirements by CMS for the purposes of this solicitation subject to the freedom of information act and therefore subject to public exposure?

A. Privately-held corporations are exempt from the requirement to submit audited financial statements to CMS if they do not have any such documents. (Of course, if you have audited financial statements, you should submit them.) If you do not have audited financial statements, we still would require some alternative documentation that satisfactorily demonstrates to us you meet the financial stability requirement (for example, unaudited financial statements and/or balance sheets). With respect to the

Freedom of Information Act (FOIA), as noted in Section 2.8 of the General Solicitation, only information that constitutes a trade secret, privileged or confidential information (as such terms are interpreted under FOIA) and are labeled as such will be protected from release by CMS.

23. May we remove the "qualifications" text and only include the "application requirements" text with our responses?

A. Yes

24. May we replace your bulleted format with a numbered format in order to facilitate our process and to better communicate with CMS as long as we clearly reference the section and don't change the order?

A. Yes

25. We are currently a M+C with a PPO Demo Project. We are considering doing two discount card offerings, one for our M+C PPO and one for all Medicare in the state. What Application(s) would we need to submit? I found that the Solicitation says that only one intent to apply is needed by the new January 7 due date, but would we need two separate Applications submitted by January 30 since some requirements are waived for M+C plans? Or since we are a contracted M+C company, would all waived requirements be waived for any plan we administer even if it covers Medicare beneficiaries who are not a part of our PPO Demo?

A. Your organization would need to submit two separate applications, one using the Medicare Managed Care Organization Solicitation and the other using the General Solicitation. For the drug card program you will offer exclusively to your M+C PPO plan enrollees, you should submit an application describing such a program using the Medicare Managed Care Organization Solicitation. Any waivers you are granted for your exclusive drug card may not be applied to the drug card program you will offer to all Medicare beneficiaries, regardless of their enrollment in your PPO plan. For the drug card plan you intend to offer to all Medicare beneficiaries residing in a particular state, you should submit an application using the General Solicitation. There are no waivers available under this solicitation (other than the waivers available to sponsors seeking special endorsement).

26. There are mistakes in the numbering of provisions in Section 3 in this Solicitation. The same numbering mistakes appear in the December 16 and December 23 versions. For example, 3.3 Service Area and Access to Pharmacies has two provisions numbered "3.3.2" - one of which is titled "Service Area" and the other of which is titled "Pharmacy Network". After 3.4 Other Drug Related Items and services..., there is another provision, 3.3 Card Program Administration and Customer Service, which means there are two 3.3 provisions. And provision 3.5.2 follows provision 3.3.1, but there is no provision 3.5 or 3.5.1. These mistakes make it difficult for those of us who are trying to use the Solicitation as a template for our card applications. When can we expect another revised Solicitation with correct numbering? Thanks.

A. A revised solicitation will be posted during the week of January 5, 2004.

27. Under section 3.5.1 Beneficiary Eligibility/Enrollment/Enrollment Fee, of the December 23rd update to the solicitation an error persists that were told would be corrected in any update. Page 31, the 5th bullet point reads, "Indicate that you will collect only the data elements described in CMS standard enrollment form shown in the model enrollment form posted on the CMS web site." At the bottom of page 28 the solicitation states that you can collect other data, as long as all the elements in the CMS standard form are included and beneficiaries are made aware that offering additional information is optional and not related to card eligibility. I believe this is the information covered at the meeting in Washington as applicable. Will you publish a clarification on the web?

A. The statement at the bottom of page 28 is correct, and we will revise the 5th bullet on page 31 to make the statements consistent.

28. Is the "Annual Zip Enrollment File" available on a media other than Cartridge. This is a non-standard media for our industry and we have no readily available means for accessing data supplied on a cartridge.

A. The files will be provided on CD-ROMs to all who request them.

29. As a Medicare managed care organization we intend to apply as an Exclusive Card Sponsor for the Drug Card Program. We currently manage pharmacy benefits for roughly 400,000 members and have had discussions with the NYS Pharmacy Society to consider administering a program for all participating pharmacies in New York State. We understand that this would require us to also submit a General Solicitation Application, but are uncertain if we would meet the criteria since we do not currently manage >1 million Rx lives. Could you please advise whether we would qualify, or if there are waivers/exception options available? We believe that a NYS Pharmacy Society sponsored Drug Card offering would be beneficial to Medicare beneficiaries as these pharmacies will engage in stronger discounts and greater support to the Drug Card program.

A. Your organization, with 400,000 members, would not qualify to operate a Medicare-approved drug discount card program. To meet the one million covered lives qualification, your organization could contract with an entity that currently operates a pharmacy benefit program, a drug discount card, a low-income drug assistance program, or some other similar program that serves at least one million covered lives. Please note that the entity with which you contract would need to provide the entire 1 million covered lives. Your organization could not, for example, contract with another entity that covers 600,000 lives to combine with your 400,000 covered lives to meet the qualification.

30. Please advise what the requirements are for Section 3.1.2 for Plans that will request a waiver. The requirement appears to be missing from the application for Medicare Managed Care Organizations.

A. Section 3.1.2 addresses the years of experience qualification for approved card sponsors. For Applicants who request a waiver of this qualification, there is no application requirement. Applicants who do not request a waiver are instructed to respond to the application requirement stated in Section 3.1.2 of the General Solicitation. This section will be clarified in a new draft solicitation to be posted during the week of January 5, 2004.

31. Please clarify the qualification requirements of a minimum of 1,000,000 lives. The Interim Final Rule references that covered lives consist both of enrollees where signatures have been obtained or fees paid. Please clarify whether a program administered by a private PBM but pursuant to state legislation where the state has created an entitlement for certain residents and those residents are automatically

enrolled without fee in the program will qualify as covered lives under the Interim Final Rule.

A. As long as the State has in fact enrolled these individuals in your program and not merely made them eligible for enrollment, your program would meet the one million covered lives qualification.

32. Can a sponsor administer multiple Medicare endorsed program designs within a state, region or on a "national" level?

A. Yes, an Applicant may submit applications to operate multiple card programs within the same service area. Each card program would have its own exclusive Medicare enrollment.

33. Under section B General Rules about Solicitation, Application, and Medicare Endorsement Period, Page 50 – Please define electronic transactions as referenced in this section.

A. This question refers to the interim final rule, which states that successful applicants will not be permitted to begin information and outreach activities unless it can demonstrate, among other things, that it has established and obtained "CMS approval of a system for conducting electronic transactions with us (or our subcontractor), including successful testing of such a system." The term "electronic transactions" refers to communicating with CMS, through telephone lines and electronic information systems, information related to such operational areas as enrollment/disenrollment, transitional assistance payment tracking, transitional assistance qualification, and price comparison reporting.

34. How and when will the Beneficiary Counts by Zip Code, and Census Bureau Population Density by Zip Code, be made available?

A. This information is available immediately to Applicants who submit a completed Data Use Agreement (Attachment 1 to the General Solicitation). See Section 2.7 for information on how to submit that document to CMS. The information will be provided on a CD-ROM and will be sent to Applicants by overnight mail.

35. Are there parameters around product changes that we may want to make to our discount card after we file our January 30 application?

A: There are a variety of parameters. Before the program goes into effect, if pharmacy and manufacturer contracts were outstanding at time of application, then you must send updated information about pharmacy networks and negotiated prices before the card program goes live. Revised price files are due to CMS contractor weekly. A notice of any price increase due to a reason other than a proportionate increase in AWP must be provided to CMS immediately. There are certain design features that can not be modified, like the annual enrollment fee for a State may not change within the year. (The fee may be modified between the time the application is submitted and the card's outreach campaign begins, provided that materials reflecting the revised fee are correct.) We must be notified immediately of any material changes in the product design, including between the time an application is submitted and when the sponsor's outreach campaign begins. Understanding that beneficiaries are locked into the program offering, we discourage product design changes over the course of the year that would not be favorable to enrollees.

36. ***ADDED 1/22/04*** - Question: The regulation appears to allow for disclosure of aggregate rebate/discount information for each discount card sponsor to entities beyond CMS, CBO and GAO. However, disclosure of some aggregate information, such as "average amount of manufacturer price concessions per brand name drug card script," which is a reporting requirement included on page 84 of the solicitation, would be potentially harmful to plans. Sponsor-specific aggregated information may be useful to CMS in evaluating the program, but it serves no purpose in the "public market."

A: We believe the questioner may be combining the confidentiality provisions in 1860D-31(i)(1) with the requirements of the Freedom of Information Act (FOIA).

Section 1860D-31(i)(1) extends the confidentiality provisions of section 1927(b)(3)(D) to drug pricing data reported by endorsed sponsors (other than data in aggregate form). So, to the extent pricing is reported in the aggregate (including average price information per drug card script), that information would not be covered by the confidentiality provisions of 1860D-31(i)(1) - which means the Secretary, could, for example, use such information for purposes other than simply carrying out section 1860D-31. However, the FOIA exemptions in 5 U.S.C. § 552(b) would still apply. Specifically, exemption (4) in FOIA states that an agency need not make available to the public under FOIA "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Thus, to the extent aggregated information constitutes privileged or confidential trade secrets or commercial or financial information, CMS could protect the information from public disclosure. We recommend that sponsors label any reported information they consider to be trade secrets or commercial or financial information that is privileged or confidential, so that we can be aware of it.

1.

Organizational Structure & Experience

1. Can an approved card sponsor continue to operate its current (non-Medicare-approved) discount drug card for their Medigap members for no fee while operating a Medicare-approved drug discount card?

   A. Approved card sponsors may continue to offer their non-Medicare-approved drug cards.

2. ***ADDED 1/22/04 -*** In Section 3.1.3, Covered Lives Concurrently (page 16-17 of the Dec. 23rd revision of the solicitation), we are asked to provide the 'Years of Experience information' for the entity meeting the 'covered lives qualification.' Is it required, then, that the entity meeting the 'covered lives qualification' meet all three of the 'years of experience requirements'? If not, what are the requirements for the entity meeting the 'covered lives requirement'?

   A: The single entity whose enrollment information fulfills the requirements of the table, 2003 Business Volumes, in Section 3.1.3 of the general solicitation, must either directly operate a pharmacy benefit program, a drug discount card, a low-income drug assistance program, or a similar program, or operate the enrollment and eligibility process as a subcontractor for such an operation. As such, the applicant must provide information concerning the firm responsible for the enrollment and eligibility of the 1 million covered lives, which includes a discussion of how the firm and the 1 million covered lives is associated with a pharmacy benefit, a drug discount card, a low-income drug assistance program, or similar program. For this firm, identify its responsibilities in meeting the qualifications, including its role in the eligibility and enrollment process. Provide a copy of the contract (or letter of agreement) that articulates these responsibilities. It is not necessary for the firm conducting the eligibility and enrollment (or even for its affiliated pharmacy benefit program, drug discount card, low-income drug assistance program, or similar program) to meet the 3-year experience requirement if another organization under the applicant's program meets the 3-years experience criterion for: adjudicating and processing claims at the point of sale; negotiating with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs; and administering and tracking individual enrollee health care subsidy of benefit in real time.

3. ***ADDED – 1/27/04 -*** If we become endorsed for a single, unique product, but would like to co-brand that product with multiple organizations, may we do that? Can each co-brander have a separate listing with a different name on the price comparison website? Do we need to identify all of our co-branders in our application, or can we add co-branders after we become approved?

   A: A single, unique endorsed card program can co-brand with as many entities as it likes. The unique program must have its own name, which will be listed on Price Comparison. To accommodate the co-branders on Price Comparison, we will include a field that lists all of the co-branders by whatever name they wish to be identified by. We would encourage sponsors to list their program's co-branders in their application, but additional co-branders may be added after receiving Medicare approval for the

program. The reason we do not want to have each co-brander listed as a separate "program" on Price Comparison is that, first, a beneficiary will not be able to search for a program by name, which reduces the need for separate listings, and second, we believe beneficiaries would be confused if their results screen shows what looks like multiple "programs" all with different names, that, in fact, have identical drug offerings, prices, and networks. Beneficiaries will be frustrated by time spent looking for differences in the programs, when, in fact, no differences exist other than its name. We believe our approach of listing all co-branders in a single field along with the other program details for the single, unique program accommodate co-branders' desires to be identified, yet reduces potential beneficiary confusion.

Contracts

1. As a card sponsor, can you establish additional subcontracting relationships throughout the term of the discount card program (e.g., organizations)? If so, does this require submission of an updated application to CMS?

    A. Card sponsors may establish additional subcontracting relationships during the term of their contract. Although this situation does not obligate the card sponsor to submit a new or amended application to CMS, the card sponsors is required to provide CMS with a notice of any change to its program that might affect its qualification for endorsement. Card sponsors are to provide such notice as soon as it occurs. With respect to a new subcontractor, when such subcontractor is responsible for an area that affects the sponsor's qualification for Medicare approval, CMS would expect to receive a description of the change (including how it will impact the card sponsor's program) as well as a copy of the executed contract.

2. Can a card sponsor close down before January 2006?

    A. Approved card sponsors will be required to sign a contract with CMS for a term beginning on May 3, 2004 and ending on the effective date of enrollment for the Part D program in 2006. A card sponsor may not terminate that contract unless it can demonstrate that CMS is not performing its obligations under the program or unless CMS mutually agrees to terminate the contract.

3. If a card sponsor uses a subcontractor who has subcontractors, does the card sponsor need to provide with the application (a) a single contract with the primary subcontractor, or (b) contracts with both primary and secondary subcontractors.

    A. Applicants need to provide only the contracts with primary, secondary or any other subcontractors for areas related to covered lives, years of experience, pharmacy network, discount and rebate negotiation, enrollment and transitional assistance eligibility, transitional assistance administration, grievance process operation, information and outreach materials development, and call center operation.

4. It appears there is an enrollment period in 2006 during which discounts must be offered. Please confirm that the actual term for which sponsor must operate the discount card program is May 2004 through the end of the Part D initial enrollment period in 2006 provided that beneficiaries enrolled in the endorsed card program have not migrated to the Part D benefit.

    A. It is correct that a Medicare endorsed sponsor must operate the discount card program is May 2004 through the end of the Part D initial enrollment period in 2006 provided that beneficiaries enrolled in the endorsed card program have not migrated to the Part D benefit. During 2006, beneficiaries may not switch cards and are not provided new transitional assistance funds. Sponsors may not charge an enrollment fee, sponsors must make negotiated prices available, and sponsors must administer on behalf of its enrollees any remaining balances in transitional assistance that rolled over from 2005.

5. Regarding the application and approval process for the endorsed Medicare discount card program, it is our understanding that the requirement regarding pharmacy contracts is that a template pharmacy contract (without rates)

can be submitted for the January 30, 2004 application deadline. We then can attach a listing of pharmacies that are expected to participate under the terms of the template contract to demonstrate how these pharmacies help meet the CMS access standards. However, it is also our understanding that these contracts must all be signed and executed by late March 2004 prior to CMS granting approval of our Medicare endorsed discount card program. Can you please provide any additional clarification/guidance regarding pharmacy contracts and the application/approval process?

A. We expect to see an indication in letters of intent (and fully executed contracts) all the terms that meet the requirements of the program. Accordingly, concerning negotiated prices (or rates), the letter of intent must indicate that savings generated from manufacturers and pharmacies through negotiations w/ the sponsor will be passed through (at least in part) to beneficiaries.

   Along with the letters of intent, the pharmacy names submitted that are associated w/ these letters of intent must represent pharmacies who have entered into such a letter of intent. Furthermore, the sponsor must attest that these pharmacies have done so. In other words, it would not be satisfactory to submit names of pharmacies who have not agreed to the letter of intent. (New contracts do not have to be signed if existing contracts meet all the requirements of the program. Also, provided that existing contracts do not disallow it, it would be allowable to amend existing contracts for terms not presently represented in the existing contracts, rather then prepare and execute new pharmacy contracts. Like the letters of intent, if submitting the terms of fully executed contracts, then the pharmacies operating under each set of unique terms must be pharmacies who have actually entered into these contracts.)

   We expect an application to provide the best estimate possible of savings to be garnered and to be shared with beneficiaries. We also expect the best possible estimate of pharmacy access using the method discussed in the application, and using only pharmacies that either are already in fully executed contracts with the sponsor that meet all the terms of the drug card program, or who have entered into letters of intent that meet all the requirements of the drug card program. After pharmacy (and manufacturer) contracts are fully executed, then we expect Medicare-approved sponsors to provide updated estimates of savings to be garnered and to be shared, and of pharmacy access using the method discussed in the application.

   The actual negotiated prices (or rates) may be submitted in March 2004 as one completed step among several that is necessary for a sponsor to begin marketing and enrollment on time with other sponsors who have completed all steps in the process necessary to begin marketing and enrollment.

   Information and outreach and enrollment cannot begin until all contracts are in place and finalized. We expect all sponsors to have their contracts in place and finalized and be able to fully operate their programs by June 2004 -- and reserve the right to terminate the endorsement otherwise.

Eligibility, Enrollment & Reconsiderations (Enrollment and Eligibility)

1. CMS described group enrollment for Medicare managed care plans, where a member can opt out of a card that the managed care plan offers. Would it be possible to get a similar provision for Medigap carriers?

    A. Medigap plans may not group enroll under the drug card program. While we understand the predicament described, the statute contemplates beneficiaries making an active choice in: 1) selecting the card best serving their needs, 2) actively deciding to enroll in the card for discounts, and 3) actively deciding to apply for transitional assistance. Different from all other potential applicants, the statute contemplates special arrangements for Medicare coordinated care plans and Medicare cost contractors, if they decide to offer an exclusive card. Specifically, among other things, the statute requires that a beneficiary only join that plan's card. Therefore, the choice of another card is not an option for the beneficiary. In this circumstance we believe that group enrollment would not undermine the statutory intent of choice among cards, therefore we allow it, with the understanding that the beneficiary may decline. Medigap plans are not precluded from assisting their members in enrolling in a card they offer, provided that beneficiaries are informed that they have an option to join another card of their choice. CMS has provided for enrollment methods for the discount card (not including transitional assistance, which requires a signed form) that include telephone and Internet possibilities. It is our expectation that this flexibility will enable sponsor organizations to develop cost effective enrollment processes for their anticipated volume.

2. Will the income for purposes of determining eligibility for transitional assistance include social security income? Will the number of household members affect this amount? Is this amount total for the household or just the members on Medicare?

    A. The income threshold includes social security income. Income belonging to the applicant or, if the applicant is married, to both the applicant and spouse (whether the spouse receives Medicare or not) will be counted. No other household members' income will be counted.

3. Will disabled adults, under age 65, on Medicare be eligible for prescription drug discounts?

    A. Yes. The program is open to all eligible Medicare beneficiaries. All drug card applicants must meet the same eligibility criteria, namely, that they are eligible for or are enrolled in Medicare Part A or enrolled in Part B and are not receiving outpatient prescription drugs under their state's Medicaid program at the time of application for enrollment in the drug card.

4. Will all Medicare eligible recipients be eligible for the discount card or just those in a certain income bracket?

    A. All Medicare beneficiaries may apply for a discount card. Income is only a consideration for the Transitional Assistance portion of the program.

5. If a beneficiary enrolls in different programs in 2004 and 2005, how will the card sponsor who provided services for the member in 2004 be notified of the beneficiary's 2005 election?

   A. Elections made during the Annual Election Period (November 15, 2004 – December 31, 2004) will return an automatic disenrollment notice to the sponsor through the CMS enrollment exclusivity system.

6. What steps will CMS take when it discovers that a member has enrolled in more than one program? Please describe the notification CMS will make to the member and the program sponsors.

   A. Individuals may not be enrolled in more than one drug card sponsor at a time. Because all enrollments must be entered into the CMS enrollment exclusivity system, we expect that this scenario will not arise.

7. With respect to the annual enrollment fee that is to be collected by the program sponsor. Is CMS envisioning any specific process? (e.g. at enrollment, monthly, quarterly, etc.?)

   A. We envision the annual enrollment fee being charged once annually. We have provided flexibility to sponsor organizations in the collection of this fee in that each organization may decide to either collect the fee with each enrollment, or bill each enrolled individual for such fee after enrollment. Remember, individuals who apply for Transitional Assistance must not be required to pay any enrollment fee. If the individual is determined eligible for Transitional Assistance, CMS will pay this fee to the sponsor on the beneficiary's behalf. If the individual is determined ineligible for Transitional Assistance s/he may elect to enroll in just the discount card (and pay the fee).

8. Will you make an enrollment form available in Spanish?

   A. Yes, we will provide a translated application shortly after the English version is made available.

9. How will the beneficiaries apply for the discount cards?

   A. The basic concept of the enrollment process is described in the regulation and the solicitation documents. Beneficiaries will complete an enrollment form, or other CMS approved method, and submit it to the discount card sponsor to whom they wish to belong. The sponsor will respond to each beneficiary with the appropriate determination and information.

10. The regulation says a sponsor cannot enroll a TA applicant in its drug card prior to an eligibility determination for TA, yet exclusive sponsors are permitted to group enroll its members, with application for TA deferred to later. Don't these rules conflict?

    A. We do not believe these rules conflict. The managed care group enrollment process includes that the required notification sent to all individuals prior to such enrollment will include information about transitional assistance, providing an opportunity to apply for it, as well as the opportunity to decline enrollment in the discount card. The statute creates special rules for members of managed care plans with exclusive drug

cards and restricts such members to enrolling in only the exclusive cards. Other individuals (who are not in managed care plans offering exclusive cards) may decide that they wish to choose another discount card (for example, one with a lower enrollment fee) if they are not determined eligible for TA. Further, exclusive card sponsors may group enroll only for the drug card. If a beneficiary applies for transitional assistance than the same steps apply for sponsors of exclusive cards as for other sponsors, namely the beneficiary must provide a signed attestation of their income and other related eligibility requirements.

11. Can the dually eligible beneficiaries who participate in the Medicare Savings Programs -- (Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiaries (SLMB) and Qualifying Individuals (QI) -- be group enrolled for TA?

A. No. They have to actively apply. However, if they do apply for TA -- QMBs, SLMBs and QIs are deemed to meet the income portion of the eligibility requirements.

12. Can a company charge a different enrollment fee for a Transitional Assistance plan than the fee charged for a regular discount card plan?

A. No. The Medicare approved discount card program includes Transitional Assistance (TA); these are not separate plans. An individual who receives TA is an enrollee of the discount card. There is an annual enrollment fee for the program of up to $30 charged by the sponsor, as it determines, to each individual for 2004 and 2005. Sponsors may not collect any enrollment fee from individuals applying for or enrolled in TA. The annual fee for discount card enrollees with TA will be paid by CMS.

13. Can a card sponsor charge an annual enrollment fee of $30 for TA eligible beneficiaries, but at the same time waive the fee for "regular" discount card enrollees?

A. No. This would not be permitted as any annual enrollment fee must be charged uniformly to all enrollees of a discount card program, within each state.

14. Has any thought been given to allowing those who apply for TA to get the discount card automatically if they are not eligible for TA?

A. Yes, CMS weighed this option carefully. While such a process may seem a convenience to certain beneficiaries, for others it may impose an annual enrollment fee that the beneficiary would be required to pay. Further, due to the limits on when an individual may change cards, such a process could also inadvertently limit choice. To ensure that all individuals are aware of their options, the notice that is sent to those who applied for TA but were found ineligible informs them that they may choose to enroll in the discount card.

15. CMS said that if a member submits an enrollment on the last day of a month, with the enrollment process taking possibly several days after that to confirm eligibility and send an ID card, etc. to the enrollee, the sponsor would not be required to give retroactive discounts or TA payments. Is this accurate?

A. Yes

16. Will a faxed signature be acceptable for Transitional Assistance enrollments?

A. Yes. Beneficiaries applying for Transitional Assistance must complete and sign an enrollment form. Sponsors may accept this enrollment form in hard copy or by facsimile.

17. Will model language be provided for beneficiary reconsideration rights?

A. Yes. CMS will provide model notification letters that include information to provide beneficiaries with their reconsideration rights.

18. Can a sponsor extend the periods described for sponsor disenrollment of a beneficiary who does not pay the annual enrollment fee, such as extend the 10 days following notification of delinquency to 30 or more days?

A. Yes. The 10 days described in the solicitation is a minimum standard so a sponsor could not offer less. The period of time must be applied uniformly to all card program enrollees.

19. What are sponsors required to document when taking enrollments over the telephone or via the Internet?

A. CMS expects sponsors interested in utilizing enrollment formats other than paper enrollment forms to develop processes that incorporate appropriate privacy, data protection and security measures. CMS security policies are available on the web at http://www.cms.hhs.gov/it/security.

An example of an acceptable process might be an individual's authorization to use a credit card to pay an annual enrollment fee as a method by which the sponsor authenticates the identity of the individual applying.

For enrollment via telephone, sponsors must document the elements included in the model enrollment form. Sponsors should also provide a process to identify the caller, which could again be an authorization to charge an enrollment fee to a credit card.

20. Do the notices of eligibility or ineligibility have to be sent in writing (hard-copy)?

A. Yes. Models of notices will be provided.

21. Does the notice of ineligibility have to include the reason why an individual was found ineligible?

A. Yes.

22. Can individuals found ineligible apply for reconsideration without documenting a change in the data used when they were found ineligible?

A. When a beneficiary applies for the discount card program (with or without TA), and is found ineligible either because of answers to questions attested to on the enrollment form, or from the CMS systems verification process, he or she is entitled to apply for reconsideration of the eligibility result. The reconsideration process will involve the beneficiary's explaining why he or she disagrees with the result, including the submission of documentary evidence where applicable.

23. How will an individual having TRICARE or other coverage be determined?

A. These questions, and others, will be on the enrollment form and the beneficiary will attest to the validity of the answers provided.

24. Is a beneficiary with M+C HMO coverage for outpatient drugs (not employer group health plans) eligible for transitional assistance?

A. Yes. The legislation provides explicitly for that.

25. May endorsed sponsors offer promotions around the annual enrollment fee offered on the card?

A. Endorsed sponsors can offer coupons or nominal gifts to offset what the beneficiary will pay in enrollment fees. If this is the intent of the question the nominal gift may not be a form of inducement to enroll the member in the card program and the coupon or gift must be offered to all beneficiaries and cannot exceed 15.00.

26. Will endorsed vendors have to print, "this is not insurance" on the endorsed card to meet various state laws?

A. Endorsed card sponsors will need to state on their card "this is not a Medicare insurance card."

27. Can enrollment fees vary across the country or regions?

A. Enrollment fees are allowed to vary by State.

28. If a beneficiary is found eligible on reconsideration, how will the sponsor know?

A. The reconsideration contractor will communicate with the CMS drug card enrollment system, which will in turn provide the sponsor with this information when an individual's ineligibility determination is turned over by the reconsideration process

29. What is the "independent reconsideration contractor" and will card sponsors need to contract with them?

A. The independent reconsideration contractor is an entity that CMS will contract with to handle the reconsideration process for this program. Sponsors will not have to contract directly with this entity.

30. Does temporary coverage under a spouse's COBRA coverage count as an "employer sponsored group health plan?"

A. Yes, it does. The exclusion from TA pertains to any outpatient prescription drug benefit offered through a group health plan or through health insurance coverage. Since COBRA coverage would qualify as insurance offered through a group health plan, such coverage would disqualify a person from receiving TA.

31. If a beneficiary has a prescription discount card already from an employer, can the beneficiary obtain the Medicare endorsed card too? If so, can the beneficiary use both cards to get a discount off the discount?

A. Yes, the beneficiary may obtain a Medicare discount card. Only those with outpatient drug coverage from their State Medicaid program (or who don't have either Medicare Part A or Part B) are excluded from participation. We do not believe that card sponsors would aggregate discounts as you suggest.

32. What period do beneficiaries who disenroll under an SEP have to reenroll without incurring a penalty, for example, losing their eligibility determination status?

A. The interim final rule states that a beneficiary awarded a special election period and disenrolls may enroll in another endorsed program at any time in the enrollment period. That period is defined as ending 12/31/2005.

We are clarifying this because the solicitation incorrectly states that the period for reenrollment is the close of the annual coordinated election, which is 12/31/2004.

33. For individuals who paid an enrollment fee in a non-Medicare discount card program (for its use in 2004) that becomes a Medicare-endorsed discount card program, can that fee be grandfathered in, or does the beneficiary need to pay the full enrollment fee again? If grandfathering is allowed, how will it work?

A: The following is an operational policy entitled, "CMS Recognition of Prior Enrollment Fees Paid for Use of Similar Card in Calendar Year 2004". **If an applicant decides to implement this policy option, then the information at the end of this answer must be included in the application.**

If the following conditions are met: a beneficiary is already enrolled in drug discount card program with features similar to the design submitted and approved for a Medicare endorsement; both cards are sponsored by the same organization; the beneficiary paid a fee for the use of the card in calendar year 2004; then the amount paid by the beneficiary may be applied by the sponsor to the standard enrollment fee charged for that similar program in that State. Under this policy, beneficiaries who do not receive transitional assistance will pay the standard enrollment fee less the prior paid amounts credited to them. For beneficiaries who qualify for the transitional assistance, CMS will reimburse the sponsor for the full amount of the sponsor's enrollment fee charged for the approved card program, and the sponsor must reimburse to the beneficiary the amount that the sponsor credits beneficiaries who do not receive transitional assistance.

For example, if the beneficiary previously paid $15, but the approved card enrollment fee is $30, then discount card only beneficiary would be charged only $15 by the sponsor. For the transitional assistance beneficiary, CMS would reimburse the sponsor $30, and the sponsor would reimburse the beneficiary $15.

The sponsor must implement this policy uniformly within a State. That is, it would apply to all beneficiaries in a State who paid the fee for use of the card in 2004. However, it is a choice whether the sponsor implements this policy or decides not to recognize the prior fee paid if the sponsor's program meets the conditions stated above. If the sponsor chooses to implement this policy option then beneficiaries must be informed about it, particularly concerning the sponsor's responsibility to reimburse the credited amount if a beneficiary who paid a prior fee also qualifies for transitional assistance.

Importantly, if an applicant wants to apply this prior enrollment fee policy to its Medicare-endorsed card program, then the following information must be included in the application in response to the general solicitation, under Section 3.5.1, under the application requirement which states, "State the annual enrollment fee (if any) you intend to charge your drug card enrollees. If different fees are charged in each State, identify the fees by State:

- Provide the following subtitle under the applicant's response to Section 3.5.1 of the solicitation: "CMS Recognition of Prior Enrollment Fees Paid for Use of Similar Card in Calendar Year 2004.

- If the application contains more than one program design, identify the specific program(s) to which this prior enrollment fee policy should apply. Indicate in which States (or indicate entire service area) in the sponsor's proposed service area the policy option will be applied.

- Describe how the existing program is similar to and different from the program(s) identified above for which a Medicare endorsement is being sought.

- Identify whether the sponsor of the existing program is the same sponsor as the applicant for Medicare-endorsement of the drug card program to which the prior enrollment fee rule would apply.

- Identify the fee amount charged and paid by enrollees in the existing program in order to use the card in calendar year 2004, including whether and how that fee has varied for use of the existing card in calendar year 2004.

- Provide sample marketing material demonstrating the enrollment fee(s) charged for use of the card in calendar year 2004.

- If different from above, state what enrollment fee amount the applicant believes should be applied against the enrollment fee that the applicant intends to charge under the Medicare-endorsed drug card program(s), and why this should be the amount applied.

- Indicate that: the applicant is requesting that the policy of CMS recognition of prior enrollment fees paid for use of similar card in calendar year 2004 be applied to enrollment in the drug card program(s) identified above; and that the sponsor will implement the policy uniformly and in accordance with CMS guidance, including the sponsor will assure the policy is only applied in circumstances where an enrollee actually paid the enrollment fee for the existing program.

34. Will there be any provisions allowed to collect the electronic signature of a Transitional Assistance (TA) eligible Medicare beneficiary via the Internet or IVR system? What if the applicant is able to demonstrate that this is currently an industry accepted practice today that can protect the confidentially of the beneficiary's personal information?

A. Each individual enrolling in Transitional Assistance must sign an enrollment form. Currently, because there is no single accepted standard for an electronic signature in this context, we will not accept signatures for Transitional Assistance enrollments other than pen and ink, or "wet," signatures.

35. Will a special enrollment period occur if a drug card sponsor has a significant discount change on a particular drug or drugs, for a reason other than increase in AWP?

A. If and when sponsors' negotiated prices increase, these changes are most likely to come from changes in AWP. However there are other potential sources of legitimate price changes under this program which are much less likely to occur throughout the course of a year, but nonetheless could be necessary for a card sponsor to assure its

ongoing program costs are being covered. We will allow price increases in an amount proportionate to the changes in a sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy. We require that a sponsor provide a notice of such change and rationale. We expect to monitor changes in drug prices. We would not allow an SEP for a beneficiary who experiences a price increase that we consider legitimate. If, however, a card sponsor increases drug prices for other reasons, then we would investigate this and consider corrective actions for the drug card, including possibly to lower the drug prices. We also reserve the right terminate approved card programs that are not in compliance with the requirements of the drug card regulation. If we would terminate such a card, then an SEP for all that card's enrollees would be granted.

36. Will State Pharmacy Assistance Programs and/or coordinating drug card sponsors be able to submit a group enrollment on behalf of enrollees?

A. No. The Medicare-approved discount card program is voluntary and the statute contemplates beneficiaries making an active choice in selecting the card that best serves their needs.

37. I know the maximum annual enrollment fee is $30, and I know we have the option to collect it up-front with the application or after the drug card is issued. As an approved sponsor that offers a Medicare-endorsed drug card, is the sponsor required to collect the enrollment fee as a one-time annual payment, or do we have the option to collect the enrollment fee as a monthly, quarterly, or some other "non-annual" method of payment?

A. The annual enrollment fee that a sponsor may charge is a one-time per year fee and therefore should be collected with one payment. We have provided some flexibility, as noted in the question, to collect this fee with the enrollment form, or bill for it after enrollment.

38. I have a question on section 3.3.1 Beneficiary Eligibility/Enrollment/Enrollment Fee: It states that the applicant contacts beneficiaries by telephone when an incomplete enrollment application is submitted. My question is, must this contact be by phone only? We hope to systematically process all discount card applications without much manual intervention in order to expedite potentially high volumes of discount card applications. We do this in the M+C world today. In doing so, we hoped that we could contact the beneficiaries by letter asking them for the missing information. The beneficiary could either call the plan with the information or send back the application with the missing information. Your feedback is appreciated.

A. Sponsors may utilize other mechanisms in addition to contact by phone to reach beneficiaries who have submitted incomplete enrollment forms. We believe that in many circumstances contact by phone could facilitate quick processing for beneficiaries and sponsors alike by relieving sponsors from the paperwork burdens and time delays associated with mailing letters.

39. If a plan receives a TA application on 6/30/04 does the plan have to make the members benefits available 7/01/04 or can the plan wait until CMS confirms eligibility which should be within 3 days?

A. The effective date of enrollment in the program, other than enrollments made during the Annual Coordinated Election Period, is generally the 1st of the month following the month the sponsor receives a completed enrollment request. In this scenario, the effective date of enrollment is 07/01/04. However, sponsors will not be required to give retroactive discounts or Transitional Assistance payments.

40. Is a plan restricted from sharing enrollment fees with network providers?

A. We expect sponsors to consider their legitimate sources of revenues and costs in establishing negotiated prices and enrollment fees, and in developing payment terms between the sponsor and its network providers. CMS does not intend to provide specific guidance on what a sponsor may establish as its enrollment fee, other than to specify (as is required in statute) that it may not be higher than $30 in either of 2004 or 2005, and may not be charged at all after 2005. Likewise, we do not intend to provide guidance on how the enrollment fee will be used. That is to say, the rules of the drug card program do not include restrictions on sharing the enrollment fees with network providers.

Additionally, medication error/ adverse drug interaction is required (1860D-31(e)(2) and pharmacies could be paid for such services, however, nothing in the drug card rule would preempt the anti-kickback statutes.

41. Will a beneficiary who has a share of cost for their Medicaid be eligible to the discount drug card? How will the expected changes for part B premiums in 2007 affect the QMB, SLMB, QI-1 and QWDI programs?

A. "Dually eligible" Medicare beneficiaries who receive outpatient prescription drug benefits from their State Medicaid program may not participate in the Medicare discount drug card or Transitional Assistance programs. Other dually eligible beneficiaries (such as QMBs, SLMBs, QIs, and QDWIs) who receive assistance from Medicaid only in paying some or all of their Medicare cost sharing obligations and who do not receive a Medicaid outpatient prescription drug benefit are eligible to apply. This set of answers only addresses questions about the drug card. Part B and other Medicare reforms will be discussed in future public communications.

42. Does an endorsed sponsor have to accept all payment terms for the enrollment fee (e.g., check, money order, credit card)? Or can the payment be restricted to credit/debit cards?

A. We believe that restricting payment to credit or debit cards could discriminate against beneficiaries who do not have or use these mechanisms to make payments. Therefore, we strongly recommend that sponsors make provisions to accept either cash or money orders. Any other legitimate mechanisms of payment are also allowed.

Drug Card Offering (Drugs, Rebates, and Discounts)

1. What are the policies and procedures for manufacturers to charge discounts and rebates?

    A. Unless a manufacturer is a Medicare-endorsed sponsor, there are no policies and procedures specific to this program for manufacturers to follow, other than to be in compliance with any applicable State and Federal laws to the extent a manufacturer is in anyway associated with the drug card program. Also, manufacturers should be aware that covered discount card drugs under this program are exempt from Medicaid best price policy. If a manufacturer is applying to be a card sponsor, then the manufacturer is required either to apply discounts to the manufacturer's own prescription drugs (for example relative to the average whole sale price), and / or to obtain rebates, discounts, or other price concessions from other manufacturers on other covered discount card drugs. Also, like any other Medicare-endorsed sponsor, a manufacturer sponsor would be required to offer a negotiated price to beneficiaries (e.g., such as a manufacturer or pharmacy discount or other price concession) on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic group in Attachment 2 of the solicitation, and would be required to also offer a negotiated price for generic drugs in at least 55 percent of these same categories.

2. How often can a sponsor add or delete products from the program? Will there be allowances to change the formulary throughout the benefit period? If yes, what notification, if any, would be required?

    A. Importantly, any products offered initially in the application for Medicare-endorsement or added later must fit within the definition of "inside the scope of the endorsement", which is discussed in II.C.5 of the Medicare Prescription Drug Discount Card Interim Final Rule. Further, material modifications to a sponsor's application must be communicated to CMS as soon as they occur. Provided that these rules are followed, a sponsor may add products at any time. A sponsor will have an opportunity once a week to change its formulary, including adding and deleting covered discount card drugs offered for a negotiated price that is reported on the CMS price comparison website and / or the sponsor's electronic media, provided that the baseline formulary requirements continue to be met, and appropriate public disclaimers are associated with these changes (as will be discussed in the information and outreach guidelines; we do not require that beneficiaries to receive advance notice of changes). Other than changes from time to time in a card's covered discount card drugs offered for a negotiated price, we would expect product and service offerings related to the covered discount card drugs to remain stable across a calendar year. To the extent that changes to products and services are necessary, particularly a deletion, then we would expect to be notified, and the sponsor's information and outreach materials to be modified, in advance of implementing the change to avoid any beneficiary confusion. At no time is a sponsor's endorsed card program allowed to be out of compliance with the requirements for endorsement.

3. How shall the "rebate and discount levels to be shared" be defined? Is there a threshold level to qualify? Does a sponsor have to obtain a contract from all manufacturers? Do all manufacturer and pharmacy rebates/discounts/other price concessions have to be passed through to the beneficiary at the point of sale?

    A. In response to the application requirement in Section 3.2.2. of the general application, which states, "Estimate the aggregate level of manufacturer rebates/discounts/other price concessions to be secured from drug manufacturers and the estimated total share that will be passed through to Medicare beneficiaries in the form of lower prices at the point of sale", an Applicant must provide a single estimated aggregate dollar amount of manufacturer rebates/discounts/other price concessions to be secured across all the sponsor's manufacturer contracts, and provide a single estimated percentage reflecting the portion of that dollar amount to be passed through to Medicare beneficiaries in the form of lower prices at the point of sale. A sponsor must have at least one manufacturer contract, and the reported estimated dollar amount and percentage share may not be zero; however, to be successful in attracting enrollees and maintaining their satisfaction under a sponsor's program, we believe a sponsor will need to negotiate manufacturer price concessions and pass through as much of the pharmacy and manufacturer price concessions as possible (e.g., after covering administrative costs), to provide competitive discounts at the point of sale.

4. Since a sponsor will receive any manufacturer rebates long after the point of sale, rather than pass through these rebates directly to the beneficiary, can the sponsor use the rebates to reduce enrollment fees?

    A. Sponsors are not required to charge an enrollment fee, but must charge the same fee to all beneficiaries within a state if they do charge a fee, and the fee may not change for the year. The expectation is that sponsors will estimate *anticipated* rebates and develop a negotiated price based in part on that estimate, and make future adjustments in negotiated prices -- up or down -- as necessary to accommodate mid-course accounting for actual rebates. (If prices increase within the year (except for the week of November 15) beyond the proportionate change in the AWP, then the sponsor must provide a notice and rationale as discussed in II.C.4.c of the drug card regulation.)

5. Can a card sponsor offer a generic only benefit?

    A. No. A card sponsor must provide a negotiated price on at least one drug in each of the 209 therapeutic categories provided in Attachment 2 of the general solicitation. Approximately half of these classes do not include Class A generics. For the categories that do include a Class A generic, the sponsor must provide a negotiated price on at least one generic in at least 95% of those categories; for such a category, a sponsor is <u>not</u> required to provide both a brand and generic drug for a negotiated price.

6. Can a card sponsor's program qualify for a Medicare endorsement without including in the negotiated prices some type of price concession obtained under contract from one or more manufacturer?

    A. No. Please refer to Section 3.2.2. of the general solicitation.

7. Can a sponsor incent the use of mail order pharmacy?

   A. Yes; however a sponsor may not require as part of the design of its drug program that enrollees use mail order. Also, any such incentives must still meet the program requirements. For example, a sponsor couldn't refund the enrollment fee to those who use mail order pharmacies.

8. When submitting participating pharmacies to CMS and providing pharmacy information to enrollees, can the list be abbreviated by saying, "all pharmacies in a certain chain (by name), are in our network"?

   A. In order to validate that a sponsor meets the pharmacy access standards, an applicant must provide the list of pharmacies as required in Section 3.3.2. of the general solicitation. In the print material provided to a beneficiary, the list must include the contracted pharmacies in the beneficiary's zip code or county. The list for a beneficiary may be abbreviated to indicate that all pharmacies in a certain chain (by name) in the beneficiary's area (zip code or county) are included in the card' s network. Any contracted pharmacies that are in the beneficiary's area that are not represented by this type of abbreviation must be listed.

9. There are several regional pharmacy corporations that are interested in obtaining a Medicare endorsement for a discount card program. While these organizations have excellent penetration in their region, their regions are not consistent with state borders. Will waivers be considered for these groups?

   A. No, waivers on service area and pharmacy access will not be granted. Sections 1860D-31(e)(1)(B) and (h)(3) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 are very clear that a program must be available to all beneficiaries within a State that is included in the sponsor's card, and that the pharmacy access standards must apply in order for a program to be endorsed by Medicare.

10. Most managed care drug formularies are comprised of 40 to 60 different drug classes. Can you comment on how the 209 classes for this program were derived and can you describe the advantages and disadvantage of drug formulary classes as outlined in the discount card solicitation (209 classes) versus the standard managed card organization drug formulary (40 to 60 classes)?

   A. The figure "209" represents the lowest level categories under therapeutic classes, subclasses, and groups in which at least one drug must be offered at a negotiated price; hence, the 209 categories do not represent only "classes." If by classes the author of the above question means high level therapeutic groupings, the baseline category list for this program actually includes only 24 such groupings. We present a thorough discussion of the methodology for deriving the 209 categories in the Interim Final Rule published December 15 in the Federal Register and available on our website at www.cms.hhs.gov/discountdrugs.

11. Fertility drugs are excluded, however, on occasion, some of these drugs are used for non-fertility purposes. How will these drugs be handled since most pharmacies do not have

access to diagnostic information. Will prior authorization be required?

A. The statute specifically states that agents used to promote fertility are excluded from the definition of covered discount card drug. Our interpretation is that the same agent when used for another purpose could be included under the definition of covered discount card drug (provided the drug otherwise meets the regulatory definition of "covered discount card drug"), and therefore a discount could be offered and transitional assistance applied under such circumstances. Prior authorization is not a required component of this program. However, should sponsors include these drugs in their programs, they should understand that they are responsible for ensuring that drugs excluded from the definition of covered discount card drugs are not part of this program. CMS will monitor and audit for transitional assistance and discounts applied to non-covered discount card drugs, and to the extent that we find such drugs as part of the program, sponsors may be asked to demonstrate that the drugs were included in the program for legitimate reasons (e.g., the example posed in the question above).

12. Can transitional assistance be applied to over-the-counter drugs?

A. No.

13. Can card sponsors include oral oncology products in their discount card offering if they are also included in the Part D Oral Oncology Demonstration project? How will drugs that are covered under Medicare under certain circumstances but not others (e.g. erythropoeitin) be handled?

A. Under any circumstances, only prescription drugs that fit under the covered discount card drug definition (42 CFR Section 403.802) may be offered under an approved drug card program for a discount and have transitional assistance apply.

If a prescription drug is within that definition, except it is sometimes or always covered under Medicare Part B, that would disqualify the drug for a discount or transitional assistance under a drug card in the particular circumstance when the drug is payable under Medicare. The Section 641 demonstration is a Medicare Part B demonstration. Therefore any drugs that are covered under the demonstration may not be offered for a discount or have transitional assistance applied to it under the discount card program. However, there could be an individual circumstance under the demonstration or Medicare Part B more generally where the drug would not be payable by Medicare. Examples include when the beneficiary does not have Part B coverage, or Medicare coverage is based on a set of clinical circumstances that the beneficiary does not meet. In these circumstances the drug may be offered to that beneficiary for a discount and transitional assistance may apply under an approved drug card.

14. Certain drugs are excluded for understandable reasons when there are transitional funds ($600) to help pay for the cost of these drugs, baldness, wrinkle, anti-obesity and other cosmetic drugs. Can these be offered at a discount to non-transitional funded members? Can they be offered at a discount to transitional funded members as long as no transitional funds are applied to these excluded products? Are over-the-counter drugs considered covered discount card

drugs? Should sponsors negotiate discounts on over-the-counter drugs? Over-the-counter drugs are on the "exclude" list in the covered discount card drug definition in the regulation. Isn't this a contradiction?

A. Over-the-counter drugs as well as certain prescription drugs, such as agents when used to promote hair growth , weight loss or weight gain, are excluded from the "covered discount card drug" definition mandated by Section 1860D-31. And, as further mandated, transitional assistance may apply only to covered discount card drugs; therefore, transitional assistance could not be applied to the drugs listed above. Sponsors also are prohibited from providing or marketing, under their endorsements, any item other than: (1) items and services directly related to covered discount card drugs and that are offered for free (except for the enrollment fee, if any, and discounts on the covered discount card drugs themselves); and (2) discounts on over-the-counter drugs. Therefore, prescription drugs that are excluded from the covered discount card drug definition may not be offered for a discount under the Medicare endorsement by the card program. However, a sponsor may both offer and market discounts on over-the-counter drugs (but not items and services related to these discounted over-the-counter drugs).

15. It appears that "Best Price" does not apply to the discount card. I interpret this to mean that we can negotiate pricing discounts in excess of those currently available to commercial purchasers, like WellPoint. Is this true? Does the Best Price exemption also apply to the insured program that will begin in 2006?

A. It is correct that best price does not apply to the Medicare-endorsed discount cards, allowing sponsors to negotiate discounts under the endorsement in excess of these currently available to commercial purchasers without having to reflect these discounts in the best price calculations for Medicaid rebates. Part D drug benefit rules will be announced in the Part D rulemaking.

16. It appears that an endorsed vendor may keep part of the negotiated discount with a pharmacy provider as revenue to support the ongoing program while passing through some portion as savings to the beneficiary. Is this prohibited anywhere in the IFR or in the forthcoming application?

A. We believe that a drug card sponsor's success at obtaining and passing through significant discounts, rebates and / or other price concessions from pharmaceutical manufacturers and pharmacies to Medicare beneficiaries will affect the desirability, and hence the competitiveness of its drug card program offering, providing a powerful incentive for sponsors to do this. Nonetheless, as the impact analysis demonstrates, sponsors will incur substantial costs to start- up and maintain their program offerings in compliance with the statutory and regulatory requirements of this drug card program (see Section III of the drug card interim final rule). Hence, there is no explicit prohibition in the interim final rule or solicitation on a sponsor keeping a portion of the rebates, discounts and other price concessions from manufacturers and pharmacies as revenue to support the ongoing program. In fact, we expect that sponsors will have to do this to cover their operating costs, depending in particular on the level of enrollment fee they plan to charge, understanding that the

level of enrollment fee, like the drug prices themselves, will also affect the marketability and competitiveness of the drug card offering. Nothing in this answer should be construed as allowing sponsors to operate in a manner that violates any other federal or state laws that would also govern behavior under this drug card program.

17. The documentation states that "Entities would be required to assure that low-income beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that was therapeutically equivalent and bioequivalent and that was available at the pharmacy or other dispenser." What is the process that CMS envisions for PBM's to do this.

A. We assume that sponsors and pharmacies have the necessary electronic databases to identify generic drugs that are therapeutically equivalent and bioequivalent to prescribed brand-name drugs. We also assume that card sponsors or their subcontractors will have the necessary IT interface with their network pharmacies and will provide the software necessary to provide a differential price at retail point of sale. Sponsors should include information in their application informing CMS about their capacity and process for identifying such generic drugs and for deriving this price differential, as well as how the beneficiary will actually be provided the information.

18. Are cosmetic drugs included in the drug card covered drug definition?

A. Agents when used for cosmetic purposes are not included in the definition. We include an extensive discussion on the definition of covered discount card drugs in the Interim Final Rule published in the Federal Register on December 15, 2003 and available on our website at www.cms.hhs.gov/discountdrugs.

19. The presenters at the pre-application conference indicated that in the application the negotiated price would be reported, as well as the description of the arrangements with the manufacturers regarding how the rebates and discounts are passed along to beneficiaries. However, the solicitation requires a listing of drugs to be covered and the prices as a percentage discount off of AWP for each drug. Which is correct?

A. All are correct and the information requested addresses different requirements. For example, reporting negotiated prices is a requirement of cooperating with the CMS price comparison website – beneficiaries will be provided with actual prices. A description of arrangements with manufacturers is part of the application requirements to demonstrate that savings, such as rebates, are garnered by pharmaceutical manufacturers for this program and under what circumstances. The request to report the listing of drugs to be offered as a percent discount off of AWP will demonstrate to CMS that a discounted amount relative to AWP will be offered and the magnitude of that discount.

20. How are sponsors required to pass through rebates to beneficiaries - can this happen retroactively at year's end?

A. No, rebates may not be paid out to beneficiaries retroactively. Real time knowledge and application of negotiated prices is an integral component of applying statutorily mandated policies of the program such as: including in negotiated prices, at a minimum, savings negotiated with pharmaceutical manufacturers; providing to the beneficiary the lower of the negotiated price and usual and customary; informing beneficiaries of the difference between the price of the brand name drug and the

lowest cost generic offered by the pharmacy that is therapeutically equivalent and bioequivalent; the application of transitional assistance to prices at the point of sale; and reimbursement to sponsors from the federally maintained Transitional Assistance Account. Therefore, there may be no retroactive adjustments due to actual rebates garnered which would affect what a beneficiary or the federal government already paid on a final payment transaction. So, for example, to the extent rebates actually garnered is a reflection of past performance, a sponsor may estimate the potential impact of rebates and accordingly establish a negotiated price to be applied to payment transactions while this negotiated price schedule developed by the sponsor is in effect, and then make mid-course adjustments to the negotiated price schedule for future payment transactions when the updated schedule is in effect.

21. Can a card sponsor do a targeted switching program to educate beneficiaries about lower cost prescription drug alternative that may be available to them? What about for OTC products (ie: Allegra to OTC Claritan)?

    A. A sponsor can educate beneficiaries generally on how to lower their out of pocket costs and to stretch their transitional dollar, for example, by presenting the benefit of savings on generic drugs relative to brand name drugs. Also, the sponsor can educate about the benefit of a specific lower cost drug if it is a covered discount card drug (i.e., a prescription drug as defined in the rule). A sponsor can provide information about the discounts it makes available on a OTC drugs. Under the marketing prohibition the sponsor cannot provide the beneficiary information about a lower-price OTC alternative if it does not offer a discount for the OTC drug. There is guidance in the information and outreach guidelines that addresses, for example, substantiating claims and making direct comparisons that a card sponsor must follow. Within these guidelines, sponsors may encourage but can not require switching.

22. If using a formulary, could a PBM utilize their existing P&T committee (providing that the makeup meets the outlined requirements) or would they be required to establish a dedicated P&T committee?

    A. An applicant may use its existing P&T committee.

23. With respect to the requirement to "….to implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use." Does this need to be real time?

    A. We understand that it is typical practice for administrators of funded benefits and the pharmacies in those administrator's networks to maintain and operate a system of electronic algorithms and clinical edits that are designed to reduce at the point of sale the likelihood of medication errors and adverse drug interactions and to improve medication use. In addition, we understand that pharmacists in filling prescriptions routinely address such issues, for example, through their availability to the consumer to answer questions, their phone contact with physician offices about certain prescriptions, and provision of written materials for consumers for example about precautions to be taken. Not all tools to accomplish the goals of medication error reduction, prevention of adverse drug interactions, and improvement in medication use are real time. For example, pharmacies and administrators of funded benefits also have protocols to follow up on aberrant patterns or individual cases of concern. It is

all these types of systems and practices that we expect to be described in applications, as well as, for example, physician detailing and making drug information available on the internet to the extent such tools will be incorporated to support accomplishing these goals.

24. What are allowable components of a "dispensing fee"? May a card sponsor, in compliance with the terms if its contracts with pharmacies share in a portion of the agreed-to dispensing fee?

A. It is our understanding that typically the dispensing fee is a negotiated fee to reimburse the pharmacy for its costs associated with dispensing a drug. Some costs incurred by the pharmacy could include fees to be paid to the sponsor for certain administrative services which at least on balance may represent a "sharing" back to the sponsor. While we are not defining the allowable components of a dispensing fee. and whether and under what circumstances a portion is "shared" as a matter of contractual terms between the sponsor and pharmacy, we remind the sponsor that all contracting terms must be in compliance with federal and State laws, including anti-kickback laws, and that our understanding of typical practice is that the dispensing fee is paid in full to the pharmacy, while sponsor fees for administrative services are represented in separate financial accounting lines.

25. Please provide an example of efforts that a sponsor could take towards on-label prescribing? What is necessitated by this requirement? (Page 69852 of the December 15, 2003 FR).

A. We recognize that without routinely collecting certain diagnostic and other clinical information, determining with certainty on a routine basis whether a drug is necessarily prescribed for a medically accepted indication would be challenging to say the least. However, there are some activities that are common practice that support this objective, like providing to the consumer written information about the dispensed drug that includes clinical indications. Also, administrators of funded benefits with the cooperation of pharmacies contribute to identifying aberrant patterns in prescribing and use, particularly of controlled substances.

26. Is the term formulary synonymous with plan sponsors list of discounted drugs? Can you clarify the difference between formulary drugs, covered drugs, and drugs found on a discount drug list?

A. The term "formulary" is synonymous with a plan sponsor's list of drugs being offered for a discount under its drug card program. "Covered discount card drugs" is the set of drugs defined by statute that are eligible for discounts and the application of transitional assistance under this program. Please see the Interim Final Rule published in the Federal Register on December 15, 2003 and available on our website at www.cms.hhs.gov/discountdrugs for a discussion of these terms. The term discount drug list is defined in the Information and Outreach guidelines, and will represent to the consumer a sample of the prescription drugs provided for a discount.

27. Must the plan sponsor include "all covered" drugs even if no discount is provided?

A. The plan sponsor must ensure that transitional assistance, when a balance remains, can be applied to all "covered discount card drugs" even if no discount is provided, when the drug is carried by the pharmacy of purchase.

28. In your Discount Card application, Attachment 2 you list a therapeutic drug list by class. I noticed that under "Insulin" you did not list insulin syringes.

A. While insulin syringes are a part of the statutory definition of "covered discount card drug", which represents the list of drugs to which a discount may be offered, and to which transitional assistance must apply if the pharmacy carries them, it is not required that a sponsor provide syringes for a discount. Sponsors may further divide the 209 categories and / or add additional categories of "covered discount card drugs" in offering a formulary. A description of how we developed such categories is contained in interim final rule and begins on page 69853 of 68 Fed. Reg.

29. Will CMS revise the "minimum" therapeutic classes listed in Attachment 2 in the general solicitation to accommodate the introduction to market of new drug products that are "first in class", i.e., create a new therapeutic class? If so, through what process will the therapeutic classes be revised? At what point will CMS expect (and enforce compliance with) card sponsors to change their formulary to accommodate the new therapeutic class?

A. The drug categories listed in Attachment 2, are intended to represent the types of drugs commonly needed by Medicare beneficiaries and, accordingly, to provide a minimum threshold that a sponsor must meet in offering discounts if a sponsor uses a formulary. Given the short duration of this program, we do not intend to update these categories. However, we think it would be appropriate for sponsors to consider as part of their formulary development and update process the advent of new therapeutic classes.

30. ***ADDED – 1/27/04*** **-** When providing the lower of the negotiated price and usual and customary price to the beneficiary, does the usual and customary price that is compared to the negotiated price have to include the dispensing fee?

A. When determining the lower of the negotiated price and the usual and customary price, the comparison methodology must assure that the final price for a drug to be paid by the beneficiary, including the dispensing fee, is the lower price.

31. ***ADDED – 2/27/04*** **–** Prior to conducting the point-of-sale transaction, can the pharmacy provide an approximate price difference rather than the actual price difference between the brand name drug and a bioequivalent, therapeutic equivalent drug?

A. Some time during the point-of sale transaction (which can be at the end of the transaction), the actual price difference between the brand name drug and a therapeutic equivalent and bioequivalent generic drug must be conveyed to the beneficiary. That information may be conveyed in print only.

Prior to the point of sale transaction, the pharmacy should offer to provide an approximate price difference. The pharmacy must provide at least an approximate

price difference before the transaction is conducted if asked for such information by the beneficiary or his/her representative.

1.

Pharmacy Network Access

1. Will the access standards be adjusted for areas in which pharmacies do not exist within 15 miles of beneficiaries (e.g., rural North Dakota, Wyoming, Maine, New Mexico)

    A. Access standards are defined by statute in Section 1860D-31(e)(1)(B) of the Act and therefore may not be adjusted for areas in which pharmacies do not exist within 15 miles of beneficiaries. We recognize that in some rural states these standards may be difficult to meet at the state level. However, we are requiring only that sponsors meet these standards at the program level, that is, across all of the states that comprise the sponsor's service area. Therefore, sponsors that wish to include rural states may need to also include more densely populated states in their program's service area in order to meet the statutorily defined access requirements. For the convenience of beneficiaries, sponsors may offer mail order. This may provide a particular convenience for beneficiaries in rural areas.

2. If "contact name" is not a data element captured in a sponsor's participating pharmacy database, will a sponsor have to pull this information from archived contracts with independent pharmacies to provide it in the applications? Would failure to provide contact name result in failing the pharmacy access requirement?

    A. If "contact name" is not a data element captured in a sponsor's participating pharmacy database and is not easily obtainable, the sponsor does not have to provide the information, but the lack of information should be so noted in the application. Failure to provide a specific contact name will not result in a potential sponsor failing the pharmacy access requirement.

3. ***ADDED 1/22/04 -*** GeoAccess assigns classifications based on the same criteria as defined by CMS through their GeoCoding software. However, GeoAccess uses additional information to determine if modifications are necessary, e.g. if a zip code classified as Suburban is completely surrounded by zip codes that are Urban, then the classification is changed to Urban. In addition, the GeoAccess software is able to assign classifications to point zips (point zips being buildings with mulit. Questions where raised by comparing the GeoAccess assigned classifications to the classifications calculated from the CMS PopDensitybyZIP.csv file. There are 1871 zip codes that have different classifications due to the explanation above. Question: Do we use the classifications assigned through GeoCoder or do we use the classifications calculated from the CMS file. We are assuming that we are to use the classifications calculated from the CMS file. Please confirm.

    A: This is correct, use CMS file since definition is in statute.

4. ***ADDED 1/22/04 -*** There are zip codes missing in the CMS PopDensitybyZIP.csv that have actual Medicare counts in the stzipq04y2002 file. We have determined that these are primarily point zips but also zip codes shown as 203XX. As these are missing in the CMS file, a classification can not be

assigned, thus those Medicare members will be excluded from the analysis. GeoAccess, however, is able to assign classifications to those zip codes. If we use GeoAccess assignments for these, then the members will not be excluded. For these missing zip codes, do we use the assignments from GeoAccess? We are assuming that we use GeoAccess assignments. Please confirm.

A: Use Geoaccess assignment and tell us what you did.

5. ***ADDED 1/22/04 -*** There are 3909 invalid zip codes in the Medicare file, that have a total of 340,768 members. These will all be excluded from the analysis. Of these, 7324 Medicare members are listed in zip code 00000 and 292,208 Medicare members are listed in zip code 99999.

   Please provide direction.

   A: Exclude them.

Transitional Assistance

1. Will SLMB/QMB individuals be required to fill out an application for transitional assistance if they are affiliated with an exclusive plan sponsor, or will they be deemed eligible (given that they should meet all of the requirements of eligibility – i.e., they can't be disqualified on the basis of having other drug coverage since there is an exception for Medicare Advantage members)?

    A. All transitional assistance enrollees must complete an enrollment form. Individuals that are SLMB/QMB or QI are deemed to meet the income requirement for transitional assistance only. All other eligibility factors apply.

2. Please confirm whether or not individuals with employer-sponsored M+C or MediGap coverage would qualify for transitional assistance.

    A. Yes. To be eligible, an individual may not have group health plan or individual coverage other than an M+C or Medigap plan. Please note, if the individual has both M+C and some other employer-sponsored health insurance offering coverage for prescription drugs, s/he would not be eligible.

3. A sponsor decides to require the $30 enrollment fee up front. A beneficiary then applies for, and receives, transitional assistance. I'm assuming the MCO must refund the enrollment fee - is this a correct assumption? How long does the MCO have to refund the fee?

    A. A sponsor may only charge the enrollment fee upfront to those beneficiaries who are enrolling in the discount card only. Sponsors must not collect the fee from beneficiaries applying for transitional assistance. In the case where a beneficiary applies for and enrolls in the discount card only, paying the applicable fee, and then applies for transitional assistance at a future date, the sponsor must refund the fee paid by the beneficiary as it will collect the fee from CMS for transitional assistance enrollees. We have not established a time requirement for the processing of this refund, but expect sponsors to react promptly to this requirement. If our experience with the program necessitates the creation of a timeframe, we will do so and provide such guidance to sponsors.

4. If a beneficiary is enrolled in a non-exclusive card, will any unused TA follow the beneficiary into an exclusive card if the beneficiary joins a plan offering an exclusive card? How is this tracked?

    A. Yes, the transitional assistance will roll over any time a beneficiary changes cards during the annual enrollment period or a special enrollment period. The MCO offering the exclusive card in your scenario would be aware of the beneficiary's new enrollment in the plan and would be expected to provide to the beneficiary information about the exclusive card and how to enroll. At the time the beneficiary enrolls, the remaining balance on the card (which is provided to the enrollment system by the present sponsor at the time of disenrollment) would be rolled over to the exclusive card.

5. If a state BC/BS plan offers a statewide prescription drug plan with copays, cost sharing and benefit maximums, would the people participating in that plan be eligible for transitional assistance? Can TA be used to pay premiums?

    A. Those people would need to meet the standard eligibility criteria for the card, as well as the standard eligibility criteria for TA. It's not likely that they would qualify for TA as it seems they would have access to an outpatient drug benefit. Most persons who receive an outpatient drug benefit are excluded. TA cannot be used to pay for premiums.

6. If a transitional assistance member disenrolls and has an outstanding subsidy remittance from a prior transaction, how will this be handled and what will be the reconciliation process for the TA subsidy fund?

    A. Transitional assistance will be provided to the sponsor only for finalized claims. Upon disenrollment, the sponsor is to report the remaining balance. The sponsor is only allowed to be reimbursed from the federal Transitional Assistance Account up to that amount. The sponsor must have in place a process for dealing with transactions that may become final after this date, and must describe this in the application. If this process holds the beneficiary liable for the balance, then the sponsor must notify the beneficiary of this possibility in outreach materials as provided in the information and outreach guidelines.

Marketing Materials & Review Process (Information and Outreach)

1. Can a plan sponsor market two or more discount card programs with different application fees and program features?

    A. A sponsor can offer two programs with different enrollment fees and program features within the same service area.

2. Are there requirements of the sponsors to print membership cards that are consistent in look, or have CMS logo, or have consistent field layouts so the pharmacies recognize the cards and easily input the required fields

    A. The information and outreach guidelines will have specific requirements for membership card and the Medicare Mark. Card sponsors will be required to follow the NCPDP standards in developing their membership cards. Further guidance will be provided in the guidelines.

3. What are the requirements or expectations for communicating the transitional assistance balance remaining to the member at the point-of-sale? Do we need to amend our retail pharmacy contracts to obtain this result? Can the balance be made available electronically such as website or interactive voice system?

    A. Card Sponsors will be responsible for ensuring that contracted pharmacies are able to provide the balance of transitional assistance at the point of sale. Therefore Card Sponsors should specify in their pharmacy contracts that the balance of transitional assistance is a service that must be provided to the beneficiary at the pharmacy. The balance of transitional assistance must also be available through the Card Sponsor's customer service phone number.

4. Will we receive materials/guidelines to distribute with discount card applications to help seniors screen for transitional assistance so we can limit the number of transitional assistance applications

    A. The information and outreach guidelines will provide guidance on how to communicate transitional assistance and the requirements. CMS has developed model materials that will assist beneficiaries in understanding transitional assistance. This information will be communicated in the model Member Handbook and Annual Notice of Change. CMS has also developed standardized enrollment forms and eligibility determination letters that provide information on transitional assistance. Card Sponsors will also be responsible for providing this information in their summary of program features.

5. As a qualified Medicare approved drug discount card provider, will we have access to Medicare enrollees' names, address and phone numbers to mail our program literature and call them to solicit their enrollment in our program?

    A. CMS will not provide names and address to sponsors for their advertising campaigns.

6. Will "file and use" use the same program managed care plans will be starting in early 2004 or will they be managed separately?

A. The file and use program under the Card program has been modeled after the program created for managed care plans, however they will be managed separately. A managed care organization that develops materials solely for the purpose of providing information and outreach for a drug card program that it sponsors must submit these materials through the drug card review processes, and the file and use policy specific to the drug card program applies. We are developing further guidance for MCOs concerning the review process, including file and use, when materials for the drug card are commingled with the MCO's marketing materials for the health plan.

7. Can a sponsor's drug discount card website contain non-card related information or links to other sites that promote products or services "outside the scope of the endorsement?"

A. In certain circumstances, which are discussed in Section II.C.9. of the interim final rule, and will also be presented in the information and outreach guidelines, card sponsors are allowed to commingle information about Medicare-endorsed features and non-endorsed features on their websites. An organization's web pages that list the full range of products and services offered by the organization, including but not limited to its approved card program, are deemed as targeting the public at-large. In these cases, card sponsors may for example, include a link to the web page(s) describing the approved card program(s). However, web pages specifically describing the approved card program and targeting current or potential discount card enrollees, may not include information about non-endorsed products and/or services. Card sponsors also may not imply that any non-endorsed features are approved by CMS or Medicare (see section 1140 of the Social Security Act).

8. Will CMS be required to review and approve marketing materials? If so should these materials be included with the application and what other materials need to be approved.

A. Card sponsors will be expected to use a variety of materials and mediums to describe their Card programs and these materials must be reviewed and approved as outlined in the information and outreach guidelines. Examples include a member handbook, enrollment forms, pharmacy directory, list of prescription drugs, member card, grievance letters, eligibility determination letters, and advertising materials such as television, radio advertisements as well as certain materials such as sales scripts, sales presentations flyers and direct mail pieces.

During the application process, applicants should submit the pharmacy listing, summary of program features and list of discounted drugs. All other information and outreach materials must be received 30 days prior to the date the information and outreach campaign will begin -- the later of April 1, 2004 or the date established in the signed agreement between CMS and the Card Sponsor -- in order to receive a timely review.

9. When can outreach and advertising for the drug card program begin, would this include advertisement on radio, TV etc? This is already occurring in parts of the country.

A. Card Sponsors will be able to begin their information and outreach campaign on the later of April 1, 2004 or the date established in the signed agreement between CMS and the Card Sponsor. A card sponsor's start date will delayed until all requirements

have been met as indicated in the Solicitation for endorsements (e.g., all contracts finalized, all materials reviewed, all system requirements met, etc).

10. In order to keep outreach costs as reasonable as possible (and to encourage outreach to the largest number of consumers) and still provide consumers enough information to make an informed decision, will CMS allow "abbreviated" lists of contract pharmacies and prescription drugs offered to be included with the materials provided to consumers that include the drug card enrollment form as long as a toll-free number and/or web address is available for more comprehensive information and/or questions?

A. Card Sponsors will need to make available in print the top 100 prescription drugs by volume, dosage and supply to which the price applies. This list will also need to include how to obtain a complete listing of drugs and the date the list was last updated. As required in 42 CFR 403.806(f)(3) of our regulation, Card sponsors are required to provide a pharmacy directory. This directory shall be provided to each card enrollee that at a minimum includes the pharmacies in the beneficiary's geographic area. Card sponsors are also required to provide communication on how to obtain additional information on pharmacy and prescription drug listings either through the Medicare Compare website or toll free customer service phone number.

11. It was mentioned that Outreach can begin on January 30, 2004. Specifically, what Outreach programs will an organization (that submits a Letter of Intent to participate in the drug card program) be able to perform beginning on January 30th?

A. Information and Outreach materials may be submitted with the applications on January 30, 2004. Information and Outreach will not begin until the later part of April or on May 3, 2004.

Payment and Financials

1. How do you foresee card sponsors billing CMS and being paid for any enrollment fee for beneficiaries receiving transitional assistance (TA)?

    A. ***Revised 2/19/04 -*** Sponsors will submit their payment requests to the Division of Payment Management (DPM) via the Payment Management System (PMS) for enrollment fees and TA subsidy expenditures. When a sponsor requests funds, DPM initiates payment through the Federal Reserve Bank in Virginia, which provides next business day payment of funds (via ACH Direct Deposit) to the sponsor's bank account. DPM is open from 7:00 A.M. to 6:30 P.M. EST on normal business days for payment requests.

2. What is the process for reimbursing the M+COs for TA members? How will the claims system work?

    A. The M+COs will be paid the same way as the non-M+CO sponsors; through the Payment Management System. This method will allow daily payment. Other payment options involving the CMS Managed Care Payment system would have limited payments to monthly. While all card sponsors are required to comply with the HIPAA transaction standards for prescription drugs, CMS will not be collecting these prescription drug claims, but rather a payment request as discussed at HTTP://WWW.DPM.PSC.GOV for reimbursement from the Treasury's Transitional Assistance Account.

3. If an individual misrepresents their eligibility for TA and CMS confirms this, but it is later determined that the individual is not eligible, who bears the liability for the funds expended on behalf of that individual?

    A. An individual who misrepresents their eligibility for TA is liable for funds expended on behalf of that individual, particularly if CMS or its contractor informs the beneficiary that subsequent eligibility information is to be provided to CMS or its contractor and the beneficiary fails to provide that information.

4. Will CMS systems accept a negative balance related to member's subsidies?

    A. Sponsors are required to submit the remaining subsidy balance monthly. When the member has exhausted their subsidy and the balance reaches zero, this monthly reporting stops. Deductions from the subsidy balance are to be based on finalized claims, so there should not be a negative balance to be reported. CMS systems will reject negative amounts. As we stated in the preamble to the final rule, "Endorsed sponsors must have a process for managing payment against an individual's transitional assistance cap to ensure that not more than the amount of transitional assistance available is provided to the individual."

5. Will CMS be sending beneficiaries statements of payments for TA funds (similar to statements that are sent for current {Part A payments)?

    A. CMS will not be sending the TA beneficiaries any statements regarding payments made on their behalf.

6. If a beneficiary gains transitional assistance (TA) on reconsideration, will the TA be pro-rated in 2005?

   A. The proration schedule is contained in the regulation (42 CFR § 403.808(b)). The regulation provides that proration of TA for individuals applying for TA in 2005 will be tied to the date the sponsor received the beneficiary's completed application for TA, and not the date on which the beneficiary is determined eligible for TA or the effective date of his or her access to TA. The beneficiary loses $150 per quarter that he or she does not submit a completed application for TA to a drug card sponsor. Consequently, the beneficiary will not be penalized if he or she is found to be eligible for TA after reconsideration in the quarter following his or her submission of a completed application for TA; rather the proration will be based on the quarter during which the beneficiary submitted his or her completed application for TA.

7. Where can card sponsors learn more about the HHS Payment Management System (PMS)?

   A. The website for the PMS is HTTP://WWW.DPM.PSC.GOV.

8. The interim final rules state that card sponsors will bill CMS monthly for transitional assistance. May card sponsors bill more frequently than monthly? Will payments be made more frequently accordingly?

   A. Sponsors do not bill CMS directly for the TA; rather the sponsor shall submit payment requests to the PMS. Section 403.822(b) establishes a minimum time basis of one month for which the Managing Trustee of the Transitional Assistance shall pay amounts certified by CMS to card sponsors. However, the reimbursement process will exceed that basis to allow billing to the PMS on a daily basis, with funds being wired the same day from the Treasury to the sponsor's bank accounts.

Price Comparison Website

1. ***REVISED – 1/27/04 -*** If prices can vary by pharmacy contract, what price goes on the price compare?

   A: At a minimum, the price will reflect the maximum price (including the dispensing fee) any beneficiary would pay for each NDC code at the point of sale at any network pharmacy within the service area.

   Card sponsors will also have the flexibility to provide additional detail – such as prescription-pricing data at the pharmacy level, pricing by income levels served, and prescription pricing by geographic region or pharmacy chain.

2. Will the slides from the conference on Price Comparison be shared on-line?

   A. Yes. The slides have been incorporated into the day 2 slide presentation, and they are available on the web at www.cms.hhs.gov/discountdrugs.

3. How often will a sponsor be able to submit price changes to CMS' Price Comparison website and how quickly will they be posted?

   A. Data for Price Comparison may be updated on a weekly basis. All card sponsors will submit their electronic drug pricing data files directly to CMS' contractor for Price Comparison, DestinationRx, Inc. All Data must be submitted by Midnight Pacific Time on Wednesday of each week. DestinationRx, Inc. will process and display the submitted data by 12:01 AM Eastern Time on Monday of each week.

4. On the Price Comparison website, why is the maximum negotiated price listed? Why not high, low and median price?

   A. Since CMS will be listing the maximum contracted negotiated price (including dispensing fees) at the pharmacy level, the need to report the low and median price is negated.

5. Can you please clarify how endorsed sponsors are to provide enrollees with negotiated prices? Will all product prices need to be disclosed? At what level? Where?

   A. Price Comparison will display the maximum contracted negotiated price (including dispensing fee) at the pharmacy level for each NDC code.

6. ***REVISED – 1/27/04 -*** Who will show up on the price comparison web page?

   A. At a minimum, all approved card sponsors that are not managed care organizations offering exclusive card programs will be represented on the price comparison website. Beneficiaries will be able to search on geographic area and by income to find cards in their area and the prices that relate to their income bracket if a card provides such price differentials.

7. ***ADDED 1/27/04 -*** Will the card sponsors have the option to submit their prescription-pricing data at the service area level instead of at the pharmacy level as outlined in the drug pricing data requirements?

A: Yes. The current drug pricing data base design provides the greatest amount of flexibility to drug card sponsors to submit their drug pricing data. Card sponsors will have the flexibility to provide prescription-pricing data at the pharmacy level, vary the pricing by income levels served, and vary the prescription pricing by geographic region or pharmacy chain. For the card sponsors that would prefer not to provide this level of prescription-pricing data, this database design is flexible enough to allow these sponsors to submit all of their prescription-pricing data in one program as long as they provide us with the maximum price that any beneficiary would pay at any of their network pharmacies.

Please refer to the Drug Pricing Data Requirements document located on the Sponsor Information: Medicare Prescription Drug Discount Card and Transitional Assistance Program page on www.cms.hhs.gov (http://www.cms.hhs.gov/discountdrugs/) for additional details regarding the submission of drug pricing data for the price comparison website.

8. ***ADDED – 1/27/04*** **-** Why did CMS revise the language in the document titled "Drug Pricing Data Requirements?"

A: Based on several comments received from prospective drug card sponsors CMS realized that the previous language used in the "Drug Pricing Data Requirements" document resulted in some confusion. CMS has revised the language in the document as of January 26, 2004 in order to clarify the data requirements and to provide prospective drug card sponsors with the necessary information to submit their drug pricing data to CMS. **Please note** that the data structure **has not** changed from what was originally posted and the associated deliverable dates for test data and actual data files have not changed.

The revised Drug Pricing Data Requirements document is available on the Sponsor Information: Medicare Prescription Drug Discount Card and Transitional Assistance Program page on www.cms.hhs.gov (http://www.cms.hhs.gov/discountdrugs/).

Reporting and Performance Monitoring

1. Will CMS further define the reporting requirements (such as the format and frequency)?

    A. Yes, as stated in the December 19th presentation on monitoring and reporting, we will provide this information via the CMS website at a later date.

2. How are you expecting sponsors to report rebates/discounts? Aggregate vs. average across all drugs and beneficiaries?

    A. This is described in Attachment 6 of the general solicitation. Further clarification, if needed, will be made available via our website.

3. What specific details must the grievance log consist of?

    A. The details are outlined in Attachment 6 of the general solicitation, please refer to it. Any further clarifications, as needed, will be made via our website.

4. Under "routine reporting requirements", CMS would like the number of "resolved grievances" and the number of "resolved grievances that favor the beneficiaries" for each month. What is CMS' definition of "resolved grievances" and the number of "resolved grievances that favor the beneficiaries". Is the second category a subset of the first?

    A. The definition of a grievance is any complaint or valid problem that the beneficiary has about the drug card or the services provided by the sponsor in relation to the drug card. Please note, if the beneficiary's complaint resulted from a misunderstanding about the rules governing the drug card and the sponsor explains the rules to the beneficiary and the beneficiary is satisfied with the sponsor's response, this is not a grievance. A "resolved grievance" is a complaint that was answered or problem that was corrected – either to the beneficiary's satisfaction (e.g., the beneficiary gets the response that he/she is seeking) or not to the beneficiary's satisfaction (e.g., the beneficiary does not get the response that he/she is seeking). This first condition, in which the beneficiary is satisfied with the sponsor's response to a grievance comprises the number of "resolved grievances that favor the beneficiaries" and this category is a subset of the "resolved grievances" category.

5. How will the CMS caseworkers be utilized? Would they be utilized when a member's grievance persists, i.e., the member took their concern to the card sponsor but was not satisfied with the response?

    A. CMS caseworkers will be CMS employees who are specially trained to understand the requirements and responsibilities of the Medicare Endorsed Prescription Discount Card program, and if necessary, investigate concerns or complaints about a specific practice of CMS-endorsed card sponsor. The CMS caseworkers will be impartial fact finders; they will not serve as advocates for any particular party, including beneficiaries and card sponsors.

    Through a national public education program, CMS will encourage beneficiaries to direct their inquiries or complaints through their card sponsor first. 1-800 Medicare Customer Service Representatives will also convey this message. However, if a beneficiary (including the beneficiary's representative) or other aggrieved party is unable to resolve the issue with the card sponsor, they will be encouraged to contact

CMS for resolution. Some of these matters will be referred to CMS caseworkers for further investigation.

6. Complaints need to be declared as either "validated" or "non-verifiable". Please define what is "validated" and what is "non-verifiable".

   A. CMS will determine that a complaint is "validated" if there appears sufficient grounds for CMS to believe that the CMS card sponsor agreement or relevant law or regulation have been transgressed. In order to make this determination, CMS caseworkers will be trained to contact a complainant to request further information regarding the facts of the complaint in order to substantiate the allegation. CMS caseworkers will also be required to contact the card sponsor as part of the information gathering process. If necessary, other information, such as marketing materials and website documentation, will be collected.

   CMS caseworkers will find that a complaint is "non-verifiable" if the complaint or beneficiary allegation cannot be confirmed--in other words, CMS cannot substantiate the alleged transgression. Complaints will also be considered "non-verifiable" if the complainant cannot be contacted or does not provide sufficient information to justify further action by CMS.

   CMS caseworkers will be working within internal timeliness standards to assure that the complaint investigation will proceed expeditiously or that the case will be “closed” in a timely manner.

Systems, including that related to Eligibility & Enrollment, as well as Transaction Requirements, Infrastructure Requirements, Testing Plan, and "Go Live" Requirements (IT)

1. During the presentation at the pre-application conference, it was stated that a systems survey was posted on the CMS website, but I cannot find the survey.

   A. The survey is titled the CMS Connectivity Questionnaire, which is now due January 7th with a sponsor's intent to bid. The CMS Connectivity Questionnaire is located at www.cms.hhs.gov/discountdrugs under the related links categories for the solicitation. Please note the document is available as a MS Word document, which is found using the zipped link, or in PDF format.

2. Will Medicare cover the cost of the T1 lines for special cases?

   A. CMS's intent is to pay for one T1 line per sponsor if that sponsor does not currently have such connectivity to the CMS Data Center.

3. Can multiple subcontractors of a sponsor be electronically connected to CMS for eligibility/enrollment?

   A. CMS's intent is to pay for one T1 per sponsor. We are expecting one set of feeds per sponsor.

4. When will the system-training handout be available electronically?

   A. We expect to issue the file formats and the finalized business requirement supporting our system development activities by January 16. Test cases will be issued in mid February.

5. If a beneficiary is enrolled in a State Pharmacy Assistance Program, may they also receive benefits under the Discount card? If they qualify for the $600 assistance and sign up for a Discount card, will they lose their benefits under the State program?

   A. Yes, beneficiaries may be enrolled under both. If a beneficiary qualifies for TA, it may be beneficial for them to participate in both so they receive $600 in federal TA. CMS cannot say what the State discount program 's enrollment rules may be in the future, but from our viewpoint, enrollment in both is permissible.

6. If a Medicare beneficiary who chooses to enroll in the Medicare-approved drug discount card program already was participating in a discount card program offered by a pharmaceutical company or other private entity (i.e., a card that is not Medicare-endorsed and pre-dated the Medicare discount card program), can the beneficiary continue to use the non-Medicare-endorsed card, as well as the Medicare-endorsed card?

   A. Yes. Enrollment in a Medicare-endorsed card would not preclude enrollment in any non-Medicare-endorsed card. It would however, preclude simultaneous enrollment in an endorsed Medicare card.

7. On what basis will the $62 million in transitional coordination of benefits (COB) funding be distributed? Can the $62 million be used for outreach, education, printing, mailing and so forth? Can the funds be used for systems changes in an SPAP contractor 's point-of-service system?

    A. The grant money to fund COB activities is part of the legislative provisions for the Part D benefit, not the drug card. CMS is analyzing that piece of the legislation and will provide guidance in the future.

8. How quickly will the enrollment forms be verified and who will notify them of their acceptance? Will all forms of income be checked or will it be a sampling?

    A. Card sponsors have up to 5 business days from the date of receipt to process an enrollment form internally. CMS verification of eligibility for those enrollments and, if applicable, transitional assistance sent in to the CMS system by sponsors should generally result in a response back to the sponsor within 48 – 72 hours. The sponsor that received the enrollment form is responsible for informing the beneficiary of their acceptance or a determination of ineligibility. All transitional assistance enrollments are subject to eligibility verification, including income amounts attested to on the form.

States

1. Can State Medicaid agencies require/mandate that card eligible recipients such as QMBs, SLMBs, QIs and other dual eligibles sign up for the card? Would it make a difference if the state allows them to disenroll voluntarily? Would it make a difference if the state paid their enrollment fee?

    A. State Medicaid programs are not permitted to establish additional eligibility requirements other than those provided for under Federal Medicaid law unless these conditions complement, rather than conflict with, Federal law and the State provides a rational purpose in support of imposing the additional conditions. If a State wishes to require that its Medicaid beneficiaries who are eligible for the Medicare-endorsed drug discount card program enroll in the program, we will review the State's proposal to see whether it meets these requirements.

2. Will those enrolled in state AIDS Drug Assistance Programs (ADAP) or state senior pharmacy assistance programs be eligible for the $600 value drug discount cards for those under 135% FPL? ADAP--and some state senior pharmacy assistance programs-- offer only limited formularies (ADAP formularies specifically relate to HIV care). Their needy, very ill patients can and do also require many prescriptions NOT on state ADAP or senior pharmacy assistance formularies. If ADAP enrollees are to be banned from the $600-value drug discount program for those under 135%, will this also be true for those only POTENTIALLY eligible for ADAP (i.e., those who haven't yet applied for ADAP or who are on waiting lists for ADAP such is the case in at least 16 states)?

    A. ADAP enrollees, persons on ADAP waiting lists, those contemplating ADAP enrollment, and those on state senior pharmacy assistance programs are all welcome to apply for the drug card and TA. The only groups “excluded” from the card are those persons receiving an outpatient Medicaid prescription drug benefit, including a prescription drug benefit through a State's pharmacy plus 1115 waiver. The groups “excluded” from TA include those just mentioned as well as persons receiving other private health plan outpatient drug coverage (such as under a group health plan or an individually-purchased health insurance policy including drug coverage). If the applicant is not in one of these excluded groups and meets the other standard eligibility criteria, they will be found eligible.

3. Do the provisions of the federal drug card program supercede state mandates? Specifically, in the State of Wisconsin health plans have a mandate to provide 80% coverage on prescriptions after meeting a $6,250 deductible for plans sold to Medicare eligible persons. The cost of the State mandated plan would not be covered by the $30 annual enrollment fee. Yet the Federal regulations state we can't charge more than $30. If the federal regulations don't supercede the state mandates this would seem to preclude any State of Wisconsin health plans from participating in the federal discount drug program.

A. It's always our hope that state and federal laws work well together. But when there is a conflict, federal law prevails. As to the question, it seems that you indicate that Wisconsin health plans are required by state law to provide 80% of the cost of outpatient prescription drugs after a (Medicare) plan member has met a $6,250 deductible. You indicate that the $30 drug card enrollment fee would not cover state costs for providing this catastrophic benefit. It was not intended to. The $30 enrollment fee is intended to meet the administrative costs for a Medicare approved discount drug card sponsor as they provide discounts to Medicare beneficiaries who purchase drugs until we transition to the Medicare Prescription drug benefit in 2006. Medicare managed care plans operating under Wisconsin state laws may apply to become a Medicare discount drug card sponsor and offer their plans to the general public or to their Medicare beneficiaries. Please refer to the other questions on managed care and Medicare beneficiaries.

4. In the case of a State entitlement discount drug program for which cards have been issued by the Sponsor and which meets or exceeds Medicare program requirements, would such card be required to be replaced by a Medicare discount card for members that have enrolled into the same endorsed sponsored program?

A. No. The statute recognizes that a beneficiary may have State pharmaceutical assistance program (state entitlement discount drug program) benefits and a Medicare drug card. Under federal law, a beneficiary is entitled to use both. However, the State pharmaceutical assistance program is at the discretion of each State's government. States are currently evaluating their existing State pharmaceutical assistance programs and can decide to keep them as they are, amend them to provide wraparound coverage to the Medicare card, or to make other changes including discontinuing them. Regardless, we hope all Medicare beneficiaries will consider all options available to them.

5. What States offer a pharmacy assistance program?

A. Many states offer a pharmacy assistance program funded by the state which operates outside of the State's Medicaid outpatient drug benefit. The programs vary in the populations they cover, the types and amounts of drugs available, and whether the program provides a discount or an actual drug benefit. While CMS does not collect this data, check out http://www.ncsl.org/programs/health/drugaid.htm for up-to-date information on these state programs. Please note that this is not a CMS website and CMS cannot vouch for the accuracy of the information on that website.

6. The issue of working with States that have an SPAP program was not addressed during the conference. If a firm becomes an approved sponsor and is selected by a State to work with them to coordinate the TA benefit to their SPAP program, can a sponsor utilize the pricing already negotiated by the state in their SPAP program, since the beneficiary would fall back to the state negotiated pricing after using their $600 benefit?

A. There are a variety of rules that guide pricing under the drug card which are discussed in Section II.C.4 of the interim final rule, including the requirement to develop and offer negotiated prices based on rebates, discounts and other price concessions obtained through pharmacy and manufacturer contracting. Also, a sponsor may vary

its negotiated prices by beneficiary characteristic (such as income) provided that the characteristic is not discriminating against, for example, vulnerable populations, and that all beneficiaries that fit the characteristic have the opportunity to receive that pricing (including the lower of the negotiated price and the pharmacy's usual an customary price). A sponsor could structure its program to accommodate a State pharmacy assistance program design, provided that the approved program meets and maintains all the requirements of the drug card program. Also, States could modify their programs to wrap around an approved card. CMS does not dictate whether or how that would occur.

7. Can a State (NJ) that has a Pharmaceutical Program for Seniors be a single sponsor for the entire State?

   A. No. Governmental entities may not be card sponsors. However, if a State contracts with a private entity to provide such services to their State, that private entity may apply for sponsorship provided that the approved program meets all of the requirements, including it must be available to all eligible beneficiaries and only eligible beneficiaries in the state.

8. Would the State receive the annual $600.00 per person as a co-pay for the first $600.00 of drug expense?

   A. No. The $600 is paid to pharmacy providers through the sponsor on behalf of the card enrollee for covered discount card drugs, and cannot be paid directly to the State. However, if the State coordinates its SPAP with a Medicare endorsed drug card sponsor, the $600 could be used to pay for drugs before any State funds would be spent, effectively saving the State that amount.

9. The Bill precludes Medicaid individuals from eligibility in discount cards, but elsewhere seems to create some exceptions to this. In particular, it appears that Medically Needy individuals, QMBs, SLMBs, and QIs enrolled under Medicaid WOULD be eligible for the Medicare Discount card - is this true?

   A. Medically Needy individuals are those individuals whose incurred medical expenses, when deducted from their income, make them poor enough to be eligible for benefits under their state's Medicaid program (which usually includes prescription drugs). In the beginning of a budget period when these individuals may not have incurred enough medical expenses to "spend down" their income to the Medically Needy level, they would not be eligible for Medicaid. During this period, if an individual were to apply for a drug card, they would not be excluded, as they would not have access to a Medicaid outpatient drug benefit at that time. If, after obtaining a discount card and possibly even TA, the individual meets his or her spend down level and qualifies for Medicaid as a Medically Needy individual, his or her drug card and any TA benefits would not be withdrawn. Once a beneficiary has qualified for the drug card program and any TA, they keep the card and any TA for the life of this interim program. A Medically Needy individual who has already qualified for Medicaid drug coverage at the time of applying for the drug card will not be eligible.

   QMBs, SLMBs, and QIs are a slightly different story. These beneficiaries receive assistance from Medicaid only in paying some or all of their Medicare cost sharing

obligations. They do not receive a Medicaid outpatient prescription drug benefit and are therefore eligible to apply.

HIPAA

1. Does a subcontractor have to be HIPAA compliant?

    A. Subcontractors to a card sponsor -- which is a covered entity -- would be business associates to the sponsor for the purpose of operating the drug card program, and as such must be compliant with the provisions of HIPAA. Additionally, subcontractors may have other operating circumstances and relationships that would invoke HIPAA compliance that would not be modified by virtue of the subcontractor's relationship to the card sponsor. We recommend that sponsors and their subcontractors carefully evaluate the HIPAA provisions in order to understand and comply with them. We refer sponsors and their contractors to the following resources for more information: http://hhs.gov/ocr/hipaa, http://www.cms.hhs.gov/hipaa/ http://www.aspe.hhs.gov/admnsimp/index.shtml .

2. Assuming a potential sponsor has access to beneficiary information as part of its Medicare Parts A and/ or B responsibilities, is it allowable to exchange that data to identify potential participants in the drug card / Part D programs?

    A. If the sponsor has access to beneficiaries' protected health information in its capacity as a business associate of another covered entity (for example, a carrier under contract with CMS), it may use or disclose such information to identify potential enrollees in its discount drug card program only if permitted to do so under its business associate contract with the covered entity. We note, however, that under the HIPAA Privacy Rule, the business associate contract generally may not authorize the business associate to use or disclose the protected health information in a manner that would violate the Privacy Rule if done by the covered entity. Since a covered entity may not use or disclose protected health information for the purposes of marketing a product or service separately provided by a third party, including its business associates, we believe it unlikely that a covered entity could authorize a business associate to use protected health information for the purpose of marketing the business associate's Medicare-approved drug discount card program.

3. If we become an approved sponsor and sell a Medicare-endorsed drug card to a base of customers, are we allowed to solicit that base of customers for other products in the future (for example, Life or Health insurance offers) if we: 1) don't use any private health information gathered in the process of issuing them the drug card as a basis for mailing to them; 2) if we don't make any references in the advertising for these other products to us being an approved Medicare-approved provider or a provider of a Medicare-endorsed drug card; and (3) we don't attempt to sell one of these other products in conjunction with, or co-mingled with the drug card?

    A. The answer depends on the role of the organization at the time it engages in the marketing activities. An endorsed sponsor may not market products and services outside the scope of its endorsement, i.e., products and services offered for an additional fee or unrelated to covered discount card drugs, or discounts for non-prescription drugs. However, if the organization performs functions other then being

a Medicare endorsed drug card sponsor, then it may engage in these marketing activities if it does so not in its roles as an endorsed sponsor, but in another capacity. Criteria for distinguishing when an organization is acting in its role as a sponsor versus another capacity are discussed in Section II.C.9 of the interim final rule. Marketing of other products may be permissible if the organization does not use individually identifiable information obtained in its role as an endorsed sponsor, the marketing is not targeted exclusively to current or potential card enrollees but to a larger or mixed (e.g. some card enrollees and others) audience, and the marketing is not commingled with the organization's drug card information and outreach materials. For example, if the "base of customers" is solely comprised of customer information collected separately from the organization's collection of drug card enrollment information, then such marketing may be permissible. In contrast, if the "base of customers" consists of information collected from drug card enrollees, then such marketing would be prohibited. Any marketing also must be permissible under the HIPAA privacy rule, and we note that names and addresses used for targeted mailings are considered protected health information under HIPAA.

4. Will network pharmacies be business associates of an endorsed sponsor under HIPAA?

A. A business associate is a person who performs a function involving the use of PHI on behalf of a covered entity. Typically in network arrangements a provider of services is not the business associate of the health plan to which the provider is contracted because the provider is performing clinical services as a professional and thus on the provider's own behalf and not on the behalf of the health plan. However, a provider of services that is performing, for example, case management or similar activities for a health plan or endorsed sponsors, would be a business associate because the provider is doing so on behalf of the health plan or endorsed sponsor, since case management and similar activities is function of the health plan or endorsed sponsor. Ultimately, whether the pharmacy is a business associate of the sponsor depends on the services it performs under its arrangement with the endorsed sponsor.

Special Endorsement – General

1. How do the qualifications to get a general endorsement differ from the special endorsement? One seems competitive. Are the rules of engagement different?

   A. There are different rules for obtaining general endorsement versus special endorsement. One big difference is that every qualified applicant will receive general endorsement, whereas we will select a limited number of applicants for special endorsement based on a competitive process. Our selection of sponsors for special endorsement will be based on the applicants' 1) understanding of the unique circumstances of the relevant pharmacy operations, in general, and how the Medicare drug discount card program may be integrated into pharmacy practices; 2) accommodation of typical operating practices; 3) prior experience working with these pharmacies; 4) extensiveness of service area and pharmacy network; 5) completeness and feasibility of the plan to operationalize the requirements of special endorsement; and 6) ability to implement the requirements of special endorsement in a timely fashion. Applicants that are interested in special endorsement for one or more of the three areas where special endorsements will be awarded (long term care, Indian Health, and the territories) should follow the application instructions in sections 4.1-4.3 of the solicitation. We also provide a discussion of special endorsement in sections II.I and II.J of the Interim Final Rule published on December 15, 2003 and available on our website at www.cms.hhs.gov/discountdrugs.

2. Since the threshold requirements include serving 1 million covered lives, it seems that it may be difficult to serve as a special endorsed sponsor without also being a general endorsed sponsor. Would a special endorsed sponsor be required to meet the 3 years experience and 1 million covered lives requirement? Can a waiver be requested?

   A. The 1 million covered lives requirement pertains to the applicant's current book of business, not its expected covered lives under the Drug Discount Card Program. Therefore, we do not feel that this particular requirement is an impediment to a sponsor choosing to offer a specially endorsed program. Applicants may recall that an applicant can request a waiver for nearly any aspect of their proposed program for special endorsement to provide access to transitional assistance through LTC pharmacies and I/T/U pharmacies, or to provide negotiated prices in the territories, including the 1 million covered lives and 3 years experience requirements. The applicant will need to demonstrate that complying with the requirement(s) would be impracticable or inefficient, or that the waiver is necessary to implement the program within 6 months or that the waiver accommodates the unique operating needs of these pharmacies, or of the process to get negotiated pries to the residents of the territories. The two areas for which we will not accept waivers under any condition are sections § 403.812 and § 403.813 of our regulations, having to do with HIPAA privacy, security, administrative data standards, and national identifiers, and marketing limitations and record retention requirements.

Special Endorsement – Indian Health

1. Does there have to be a negotiated price for those AI/ANs that purchase drugs outside of the I/T/U pharmacies?

    A. It is important to recall that the provisions of special endorsement concern I/T/U pharmacies, not American Indians/Alaska Natives (AI/ANs), per se. The answer to the question is yes: so long as the AI/AN purchases his/her drugs at a network pharmacy, any discounts made available to card enrollees in general must also be made available to the AI/AN without distinction. Similarly, transitional assistance, if any, must be allowed to apply to any negotiated price (or usual and customary price, if lower) for the drug being purchased at a network pharmacy.

2. Is the number of special sponsors for the I/T/U access limited to 2 per state or two nationally?

    A. Neither. We intend to award special endorsement to as many sponsors as necessary to ensure that all I/T/U pharmacies in all states have the option to join the networks of at least two endorsed programs. Accomplishing this may require our awarding special endorsement to more than two sponsors nationally or within a state.

3. What will CMS do if there are not enough participants in the special endorsed program to provide access to AI/ANs using I/T/U pharmacies?

    A. Given the structure of the competitive process for this special endorsement and the incentives we developed, we believe there is a good business case for certain types of sponsors to offer this product and therefore we believe we will be able to award enough special endorsements to ensure that all I/T/U pharmacies have the opportunity to participate in the networks of at least two sponsors.

4. In the preamble of the drug card rule there is no mention of I/T/U pharmacies being able to continue to purchase off of the Federal Supply Schedule. Why?

    A. On page 235-6 of the version of the preamble available at www.cms.hhs.gov/discountdrugs, we discuss that CMS will provide technical assistance to special endorsed sponsors to help them understand the operations of I/T/U pharmacies. As one example we mention that I/T/U pharmacies purchase drugs off the Federal Supply Schedule. We anticipate that I/T/U pharmacies will continue to do this. This is why we have an explicit requirement that I/T/U pharmacies must be allowed, in their contracts with sponsors, to limit their services to AI/ANs only.

5. If an AI/AN goes out to a private pharmacy, does IHS have to reimburse under the special endorsement?

    A. Any rules that would govern IHS coverage of drugs purchased from private pharmacies are germane to IHS and not to the Medicare Drug Discount Card.

6. How does it work if a beneficiary has one discount drug card and then qualifies for access to I/T/U pharmacies?

    B. Generally speaking, we think it's a matter of education that AI/ANs learn about the availability of these special endorsed cards to the extent they purchase their drugs through I/T/U pharmacies, and a matter of encouraging beneficiaries to consider enrollment in such a card. Further, we interpret this question to be asking if an

American Indian/Alaska Native signs up for a discount card with general endorsement, and then later determines he/she would benefit more substantially from joining a special endorsed card, what options would be open to that individual. CMS has the discretion to allow a Special Election Period (during which an individual may switch endorsed cards) due to "exceptional circumstances" as determined by the Secretary. Thus, the individual could apply for a special election period due to exceptional circumstances or wait until the annual coordinated election period to select the different card. Sponsors should consult with CMS when individuals ask for an SEP for an exceptional circumstance and it is likely we would consider this to be an exceptional circumstance.

Special Endorsement – Long Term Care

1. Some LTC residents purchase their own drugs; do these residents have to use a LTC pharmacy or can they use a local pharmacy under the drug card?

   A. For the purposes of the Medicare Drug Discount Card Program, we have defined long term care facilities to mean skilled nursing facilities and nursing facilities. In both settings the Medicare conditions of participation provide for safe drug distribution practices, thereby making it possible for skilled nursing facilities and nursing facilities to control how their patients can receive medications, and that the effect of these conditions of participation is that skilled nursing facilities and nursing facilities may restrict which pharmacies supply drugs and pharmacy services to their patients. The requirements of special endorsement apply only to long term care facilities as we have defined them and nothing under the Medicare Drug Discount Card Program changes the nature of drug distribution in these facilities. Therefore, if a long term care facility restricts which pharmacies may supply drugs and pharmacy services to its patients, residents of such facility may not use their drug cards at other pharmacies.

   We believe the questioner may be asking about residents of assisted living facilities. Some residents of assisted living facilities purchase their drugs outside the facility's pharmacy and manage their own drug regimens. Also, Medicare has no regulatory jurisdiction over these facilities, as they are not Medicare providers, and the State regulations that guide prescription drug distribution and pharmacy practice in these institutions vary by State. It is a matter of educating residents of assisted living facilities to seek guidance from an administrator of the facility regarding whether their prescription drugs can be purchased at a pharmacy participating in the network of an endorsed sponsor. Eligible beneficiaries in such facilities may join any regularly endorsed discount card program in their service area and they must use a network pharmacy to obtain discounts and apply transitional assistance under the program.

2. Are sponsors required to provide negotiated prices to residents using a card under the special endorsement?

   A. No. The requirement is for specially endorsed sponsors to process transitional assistance. The actual fee schedule to be used is up to the individual pharmacy and the special endorsed sponsor.

3. At one point OPM required that FEHBP pharmacies be available to beneficiaries in the LTC facilities, yet you suggest that Medicare conditions of participation recognize that Medicare residents give up their choice of pharmacy by virtue of their decision to reside in that SNF or NF. How does this FEHBP requirement square with the lock-in under Medicare?

   A. As a patient safety protection, Medicare conditions of participation do provide that nursing home and skilled nursing facility residents can receive medications from facility staff **only** through the facility's pharmacy. Assuming that a resident also has FEHBP coverage and that Medicare is the primary payer, the FEHBP plan would pay for medications provided to the resident that are not covered under Medicare's benefit if the facility's pharmacy is part of the plan's pharmacy network. If it is not part of the network, a less generous out-of-network benefit may be available. In some cases, however, the plan may have a in-network pharmacy benefit only, in which case the medications would become the beneficiary's liability. Most Medicare beneficiaries are enrolled in FEHBP plans with broad pharmacy networks. Specific questions above FEHBP prescription drug coverage in a nursing home should be addressed to the relevant FEHBP plan.

   The drug card statute (which is not a Medicare drug benefit, and therefore does not implicate FEHBP as a secondary payor) requires that residents in LTC facilities and who enroll in the drug program have access to their transitional assistance through the LTC pharmacies serving such facilities. We are providing for this arrangement under our regulations in Section 403.816, and discussed in Section II.I of the preamble of the drug cad interim final rule.

4. What does the pre-application slide on special endorsement for LTC pharmacies mean that a beneficiary is “locked-in” to their LTC pharmacy?

   A. Beneficiaries are not locked into any particular LTC pharmacy by virtue of their enrollment in a Medicare approved card program operating under a special endorsement. Rather, the term “lock-in” as used in this slide was meant to indicate that Medicare conditions of participation for SNFs and NFs require these facilities to put in place a variety of quality controls that operationally drive SNFs and NFs to contract with LTC pharmacies to meet these COPs. To maintain this quality assurance, SNFs and NFs may, and generally do, require their residents to receive their drug therapy only through the facility’s contracted LTC pharmacy.

5. Is it possible, through the LTC special endorsed sponsorship, for a PBM to offer discounts to LTC residents who do not have transitional assistance?

   A: While CMS does not control the nature of applications that may be sent in, our guidance in the solicitation about the special endorsement to provide access through LTC pharmacies concerns only the administration of transitional assistance.

   In order for an applicant to successfully argue that it is beneficial to add a discount only feature to the transitional assistance program design for special endorsement, the applicant would (at least) have to make a compelling argument that LTC pharmacies would be interested in joining the sponsor's network to provide access to discounted covered drugs for Medicare residents who qualify for the card only (not for

transitional assistance). If LTC pharmacies would not be willing to participate, that would undermine the goal of the statute to provide access to transitional assistance to residents in LTC facilities. Our limited experience, and the experience of the private sector with drug discount card only options, is that LTC pharmacies do not participate in them.

Special Endorsement – Territories

1. Isn't mail-order illegal in Puerto Rico?

   A. Based on our research, mail order is occurring in Puerto Rico, and that certain Puerto Rico laws have been held by the Federal Appeals Court of the First Circuit not to apply to mail-order pharmacies, see National Pharmacies, Inc. v. Feliciano-De-Melici, 221 F.3d 235 (1st Cir. 2000). We continue to review this issue.

2. Please explain the $35 million grant.

   A. Section 1860D-31(j)(2)(C) of the Medicare Prescription Drug, Improvement, and Modernization Act provides that territories with approved transitional assistance plans will receive in the aggregate a one-time grant in the amount of $35 million for the duration of the Medicare Drug Discount Card Program. Interested territories will submit plans to CMS which describe their proposals for providing drug assistance to eligible beneficiaries. The $35 million will be divided across the territories with approved plans based on the number of eligible beneficiaries per region. Endorsed sponsors under the Medicare Drug Discount Card Program will not be involved in administering transitional assistance in the territories unless they enter into a separate arrangement with the territory to do so. We provide a complete discussion of this topic in section II.J of the Interim Final Rule published in the Federal Register on December 15, 2003 and available on our website at www.cms.hhs.gov/discountdrugs.

3. Can a sponsor serve only one territory?

   A. No. A sponsor receiving special endorsement for the territories must serve all the territories.

4. Do you know the number of Medicaid beneficiaries within the 600,000 who could qualify for a discount card? Why would they need a discount if Medicaid is paying?

   A. Even though there may be a considerable number of dually eligible beneficiaries in the territories, Medicaid status will not be considered in whether a Medicare beneficiary may be eligible for the drug card benefits in the territories. The law recognized that federal funding for Medicaid in the territories is capped and does not meet the entire need for Medicaid services (including prescription drugs) as it does in the states. Recognizing this difference, the law provides that territories shall not exclude Medicare beneficiaries from participating in their unique TA plan because they have access to Medicaid.

Coordination of Benefits

1. Considering that it is inevitable that some beneficiaries will present 2 cards at a pharmacy, (e.g. discount card and State card) how does that get sorted out and by whom?

   A. The following answer is predicated on the policy that Medicare beneficiaries may only be enrolled in one Medicare-endorsed discount card program at a given point in time, but that they may also continue to hold and use other non-endorsed discount cards to the extent that such cards remain available and their use is not restricted by the rules promulgated by the firms that provide such non-Medicare endorsed cards.

   If a beneficiary holds both an endorsed and a non-endorsed card, we expect that the discount on only one card would be used. Otherwise the pharmacies and manufacturers that negotiate discounts and rebates with the card sponsors would experience a cumulative effect on a single purchase. Beneficiaries should use the discount card of greatest value at a particular the point of sale. It is the ultimate responsibility of the beneficiary to determine which is the greater value, since the Medicare drug card program has no purview over other drug cards. In the market place today, pharmacists and other providers sometimes provide assistance in making this determination and we expect that practice will continue.

   So for example, take a beneficiary who qualifies for the Medicare-endorsed card and also for transitional assistance, who also has another discount card. If the discount on the same drug is more substantial on the non-Medicare endorsed card, then the beneficiary will have to choose whether it is of greater value to him / her to: 1) pay the price under the non-Medicare endorsed card that provides the deeper discount, or 2) pay a small coinsurance amount relative to the price offered under the Medicare-endorsed card, taking advantage of the beneficiary's available transitional assistance. Another more complex choice point is to determine whether the non-Medicare endorsed discount card makes available a generic substitute, and whether the price for such a substitute drug is better under the Medicare-endorsed or non-Medicare discount card. Beneficiaries (or their representatives) can check the CMS price comparison website, or call the sponsor's toll-free phone line to get price information for the Medicare-endorsed cards.

Other

1. How many of the 4.7 million people you estimate would be transitional assistance enrollees are in M+C?

    A. There are 7.3 million beneficiaries estimated to enroll in the drug card in 2004, with an estimated 4.7 million qualifying for transitional assistance and an estimated 2.6 million qualifying for the discount card only. Of the estimated 4.7 million transitional assistance enrollees, about 1.2 million are estimated to be in M+C. Of the estimated 2.6 million discount card only enrollees, the vast majority is assumed to be in Medicare fee-for-service. The major reason why the vast majority of the 2.6 million are assumed to be in traditional Medicare is that enrollment in the drug discount card only component is assumed to occur predominantly among beneficiaries without drug coverage, and many beneficiaries in M+C have drug coverage.

2. Can you tell me how the 10-20% discount that will be offered with the Medicare drug card will be funded? Will a PBM just dictate that they will pay 80-90% of what had been the usual charge and let the pharmacies absorb the loss? How are the rebates negotiated by the drug card sponsors to be passed on to the patient and the pharmacy? How are rural pharmacies to cope with the loss of patients to mail order when the card sponsors offer a discount for using their mail pharmacy to obtain a 90 day supply, but do not offer the same discount for purchase at the local pharmacy? This practice is already in effect and funnels significant business to mail pharmacies. I would put the last nail in the coffin for many rural pharmacies.

    A. We anticipate that savings in the form of "negotiated prices" to be provided to Medicare beneficiaries enrolled in a Medicare-endorsed drug card program will be generated through negotiations for discounts, rebates and/or other price concessions (and represented in contracts) between the drug card sponsor and pharmacies, and between the sponsor and pharmaceutical manufacturers, in a manner similar to how discounted prices are provided to beneficiaries of privately funded drug benefits today. CMS does not require, and has no policy concerning whether, a pharmacy accepts the drug discount terms offered by a sponsor. However, a sponsor must engage enough pharmacies to be in their retail pharmacy network to meet the pharmacy access standards mandated by Section 1860D-31 of the Act. In particular, there is evidence that rural pharmacies generally provide a less significant discount on prescription drugs then do other pharmacies in their funded business lines that are managed today by PBMs, in part likely due to the need for rural pharmacy participation in networks in order to meet the network access requirements of the funded businesses.

    In order for Medicare-endorsed card programs to be competitive they will need to offer significant discounts on prescription drugs relative to other drug card offerings in order to attract and maintain Medicare enrollment under the drug card program and to have a favorable reputation with Medicare beneficiaries in anticipation of operating under the Part D drug benefit. Therefore, it would be in a sponsor's business interest

to obtain the best rebates, discounts and other price concessions possible from pharmacies and manufacturers, and then pass through as much as they can in the form of lower prescription drug prices to beneficiaries.

Mail order does provide convenient access to certain beneficiaries today who have drug coverage, so we anticipate that card sponsors will offer it in an effort to be competitive. However, sponsors are precluded from offering mail order only programs and / or from requiring beneficiaries to use mail order. The statutory provisions mandating the drug card program are silent on the issue of retail pharmacies and 90 day supplies.

For information about the estimated impacts of this statutorily mandated program on retail pharmacies, the reader is referred to Section III of the drug card interim final rule.

3. Do you have a complete outline of the benefit structure and coverage policies of Medicare Part D?

   A. The website www.cms.hhs.gov/medicarereform provides information related to Medicare Part D.

4. For this $35 million grant to be provided to the territories, please provide an estimate of the per person amount of assistance.

   A. CMS has not calculated that. The law provides that a territory will be given funding only to provide transitional assistance for Medicare beneficiaries at or under 135 percent of the poverty level. However, territories have considerable flexibility in how to use those funds and distribute them across their eligible beneficiaries. Territories are not restricted to an even, per-capita distribution methodology. The plan that each territory submits for CMS approval will outline how the territory will ensure that these funds are spent appropriately.

5. If our health plan participates in a class action suit against a drug manufacturer during the period of time in which the interim drug benefit program is live, if there is a monetary settlement awarded, is there a corresponding obligation to pass on the awarded monies to the individuals who purchased the drugs or is there another acceptable use of the monies that we could show to benefit the member?

   A. Without knowing the details of such a case (e.g., the basis of the cause of action, the members of the class, the terms of the settlement) CMS cannot answer this question. CMS would expect that in the event that Medicare beneficiaries were harmed (e.g., overcharged for a covered drug) as a result of the conduct which was the basis for the lawsuit, the card sponsor would compensate its card enrollees in an equitable manner.

6. Is there a small business participation goal for this procurement?

   A. The statutory language under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which provides for the drug card program, includes explicit provisions for beneficiary access to transitional assistance through long term care and I/T/U pharmacies (both would likely meet the small business definition), and accordingly CMS provides regulations to facilitate their inclusion in Medicare-

endorsed pharmacy networks under a special endorsement that recognizes the unique operating environments of these pharmacies. Additionally, the statute mandates a pharmacy access standard that we believe provides negotiating leverage to retail pharmacies, as sponsors will need the participation of most pharmacies in their defined service areas to meet the access requirements. The potential impacts of this statutorily mandated program on retail pharmacies (and other small entities) is discussed in Section III.H. of the interim final rule, including alternatives considered in developing the program that mitigate potential effects of this program on small pharmacies.

7. We are a FQHC with a pharmacy in our building. If a patient comes in and presents a Medicare discount card, how do we handle it? Will we be required to file a claim and if so will we be allowed to file on a HCFA-1500? Please send me more information on what the pharmacy is required to do.

   A. You would only provide a discount or apply transitional assistance under the Medicare drug card if you are a contracted pharmacy in a Medicare-endorsed card sponsor's network. Medicare-endorsed card sponsors will be managing the transitional assistance on behalf of the federal government, and as such will be business associates to CMS, and must comply with any applicable HIPAA payment transaction standards. The sponsor may also require a certain transaction standard for processing the discount only purchases for which CMS funds are not involved. Details about the transaction standards that apply to pharmacy claims can be found at http://www.cms.hhs.gov/hipaa/.

8. ***ADDED 1/22/04*** - Where can information about the CMS FTS2001 telecommunications contract be obtained as well as instructions on how the Health Plan can integrate its existing customer service numbers into this system?

   A: MCI is the FTS2001 vendor for CMS. Information on MCI's FTS2001 contract can be found at mci.com under Enterprise/Government Services. In addition, information can be found under the General Services Administration site, gsa.gov. Once awards have been made, CMS and MCI technicians will work with the sponsors to set up FTS2001 services. CMS will continue to monitor the functionality of the services. There is no plan to integrate existing customer service numbers into the system, unless these service numbers are primarily engaged in CMS business.

9. ***ADDED 1/22/04*** - The direct transfer of phone calls from 1-800-MEDICARE to our call center will require voice lines between CMS and our call center. Will this require additional T1s from CMS?

   A: Yes.

10. ***ADDED 1/22/04*** - Will CMS pay the T1 fees, including the long distance transport charges?

    A: Yes. CMS will be directly billed for all usage charges associated with the lines.

11. ***ADDED 1/22/04*** - Will 1-800-MEDICARE customer service representatives be informed regarding existing state options

providing state-sponsored prescription drug benefits or discount programs?

A: State-sponsored program information is currently in the Prescription Drug and Other Assistance Programs tool in medicare.gov and our CSRs do use the tool when appropriate. If these programs are still offered once the drug discount cards become available, they will still be listed in the tool.

12. ***ADDED 1/22/04*** **-** What is the specific name of the discount card program that CMS has decided upon to market the program to eligible individuals?

A: CMS decided not to name the program as a whole entity. We are using "Medicare-approved drug discount cards" in our education materials.

13. ***ADDED 1/22/04*** **-** As far as outreach to beneficiaries alerting them of the discount cards, will the mailed materials be translated into languages other than English and Spanish?

A: CMS currently plans to produce national education and outreach materials in English, Spanish, and Braille. This is consistent with all of our national education efforts, including services on the Medicare website and through the 1-800-MEDICARE call center. CMS works closely with community-based organizations through our regional offices to provide assistance to beneficiaries who have communication barriers because of literacy, language, location or culture.

14. ***ADDED – 1/27/04*** **-** The regulation appears to allow for disclosure of aggregate rebate/discount information for each discount card sponsor to entities beyond CMS, CBO and GAO. However, disclosure of some aggregate information, such as "average amount of manufacturer price concessions per brand name drug card script," which is a reporting requirement included on page 84 of the solicitation, would be potentially harmful to plans. Sponsor-specific aggregated information may be useful to CMS in evaluating the program, but it serves no purpose in the "public market."

A: We believe the questioner may be combining the confidentiality provisions in 1860D-31(i)(1) with the requirements of the Freedom of Information Act (FOIA). Section 1860D-31(i)(1) extends the confidentiality provisions of section 1927(b)(3)(D) to drug pricing data reported by endorsed sponsors (other than data in aggregate form). So, to the extent pricing is reported in the aggregate (including average price information per drug card script), that information would not be covered by the confidentiality provisions of 1860D-31(i)(1) - which means the Secretary, could, for example, use such information for purposes other than simply carrying out section 1860D-31. However, the FOIA exemptions in 5 U.S.C. section 552(b) would still apply. Specifically, exemption (4) in FOIA states that an agency need not make available to the public under FOIA "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. s. 552(b)(4). Thus, to the extent aggregated information constitutes privileged or confidential trade secrets or commercial or financial information, CMS could protect the information from public disclosure. We recommend that sponsors label any reported information they consider to be trade

secrets or commercial or financial information that is privileged or confidential, so that we can be aware of it.